In the United States Court of Federal Claims

No. 16-864
(Filed: 20 July 2021[*])

J.,	*	
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Petitioner,	*	Vaccine Act; Tdap Vaccine; Transverse Myelitis ("TM"); Molecular Mimicry.
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Robert J. Krakow, Law Office of Robert Krakow, P.C., New York, NY, for petitioner.

Catherine Stolar, Trial Attorney, with whom were *Gabrielle M. Fielding*, Assistant Director, *Heather L. Pearlman*, Acting Deputy Director, *C. Salvatore D'Alessio*, Acting Director, and *Brian M. Boynton*, Acting Assistant Attorney General, Torts Branch, Civil Division, Department of Justice, Washington, D.C., for respondent.

OPINION AND ORDER

Petitioner I.J. ("petitioner" or "I.J.") moved for review of Chief Special Master Corcoran's decision that petitioner is not entitled to compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1–300aa-34 ("Vaccine Act"). Petitioner claims the tetanus-diphtheria-acellular pertussis ("Tdap") vaccine he received on 22 July 2013 caused him to suffer transverse myelitis ("TM"). The Chief Special Master denied compensation and found "insufficient preponderant evidence offered in this case stands for [p]etitioner's contention that the Tdap vaccine can cause TM, or that it did so in this case." *J. v. Sec'y of Health & Human Servs.*, No. 16-864, ECF No. 125, at 2 (Fed. Cl. Spec. Mstr. Apr. 2, 2021) ("Decision") (emphasis omitted). Petitioner filed a motion for review of the Chief Special Master's decision, contending the decision was arbitrary and capricious, constituted an abuse of discretion, and was contrary to law. For the following reasons, the Court **GRANTS** petitioner's motion and **REMANDS** this case to the Chief Special Master for further proceedings consistent

[*] This opinion was initially filed under seal pursuant to Vaccine Rule 18(b) of the Rules of the Court of Federal Claims. The Court provided the parties 14 days to submit proposed redactions, if any, before the opinion was released for publication. Neither party proposed redactions. This opinion is now reissued for publication in its original form.

with this opinion. Additionally, the Court **GRANTS** petitioner's motion for leave to exceed the page limit.[1]

I. Background

On 2 April 2021, the Chief Special Master reissued a public version of his sealed 4 January 2021 decision in this case. *See* Decision at 1. As the basic facts of this case have not changed significantly since the Chief Special Master's 4 January 2021 decision, the Court's recitation of the background facts draws from the Chief Special Master's decision.

A. Petitioner's Medical History Prior to Tdap Vaccine and Onset of Symptoms

I.J. was a healthy and active thirty-four-year-old male with no significant past medical history. Medical Records, ECF No. 8-2 ("Med. Recs. 8-2") at 8 (NYU hospital records). I.J. has a family history significant for thrombophilia. *Id.* at 65. I.J. received a Tdap vaccination on 22 July 2013. Medical Records, ECF No. 8-1 ("Med. Recs. 8-1") at 1 (Vaccination and related records). The administering nurse noted no complications or immediate reactions to the vaccine. *Id.* at 1–2.

Two weeks after vaccination, on 6 August 2013, I.J. reported "minor cold" symptoms but felt he quickly recovered from the symptoms. Med. Recs. 8-2 at 8. On 8 August 2013, I.J. experienced the symptoms leading to hospitalization. *Id.* at 7. I.J. first experienced a "fire-like" sensation that started in the right side of his upper back around the shoulder blade. *Id.* The pain quickly radiated to his chest and down both arms. *Id.* On top of the pain, he began experiencing a persistent tingling in both of his arms. *Id.* The symptoms continued to worsen and eventually the pain and tingling spread to both of his legs. *Id.* at 8. When I.J. started experiencing weakness in his arms and legs, he decided to go to a hospital. Transcript, ECF No. 103-104 ("2019 Tr.") at 15:19–17:20 (Transcript of oral argument in front of Special Master on 23 October 2019). I.J. walked to the NYU Medical Center, where he was immediately admitted to the emergency department. *Id.* Within hours of being admitted, I.J. lost the ability to use his extremities and developed urinary retention. *Id.* at 27:10–13, 29:1–4.

B. Diagnostic Testing, Initial Treatment, and Follow-up Treatment

On 8 August 2013, I.J. received his first magnetic resonance imaging ("MRI") in the emergency department. Medical Records, ECF No. 50-2 ("Med. Recs. 50-2") at 1–2 (Report printed from DVD for MRI cervical spine with and without IV contrast bone performed on 8 August 2013). The MRI revealed increased T2/STIR signal "predominantly within the central gray matter of the cervicothoracic cord extending from C3 to T1-2 level, most prominent from the C6 to T1 level." *Id.* at 1. The radiologist's impression of the MRI, which the ER physician agreed, was of a "long segment, central increased signal within the cervicothoracic spinal cord

[1] Petitioner filed a motion for leave to exceed the page limit contemporaneously with filing his motion for review. *See* Mot. for Leave to File a Mem. Exceeding 20 Pages Accompanying a Mot. for Review, ECF No. 117. Respondent indicated at oral argument the government does not oppose the motion. *See* Transcript, ECF No. 128 at 5:8–10.

without enhancement compatible with transverse myelitis."[2] *Id.* at 1–2. I.J. also received a CT angiogram during his workup, which revealed no vascular abnormalities and was characterized by the doctor as an "unremarkable CT of the abdomen and pelvis." Medical Records, ECF No. 50-1 ("Med. Recs. 50-1") at 1–2 (Report printed from DVD for CT angiograph abdomen with IV contrast performed on 8 August 2013).

On 9 August 2013, I.J.'s treating neurologist, Dr. Stephen Galletta, observed the timeline of I.J.'s symptoms developing over the course of six hours, as well as I.J.'s MRI findings, the extremity weakness, and the loss of reflexes, were all consistent with a TM diagnosis. Med. Recs. 8-2 at 20. Dr. Galletta nevertheless proposed several additional differential diagnoses, including West Nile Virus ("WNV"), Neuromyelitis Optica ("NMO")[3], and Acute Disseminated Encephalomyelitis ("ADEM")[4]. *Id.* He believed the "high signal extending down the anterior part of the cord" and the signal concentration in the ventral horns further supported his suspected TM diagnosis. *Id.* Dr. Galletta recommended a spinal tap (lumbar puncture) to rule out varicella-zoster virus[5] ("VZV" or more commonly known as shingles) and WNV, oligoclonal bands to rule out multiple sclerosis, a brain MRI, vasculitis screen, and a Lyme and Syphilis serology to rule out differential diagnoses of each virus. *Id.* While being tested for differential diagnoses, I.J. received five days of IV solumedrol and started a treatment of intravenous immunoglobulin ("IVIG") to treat TM. *Id.* The lumbar puncture revealed I.J.'s cerebrospinal fluid had normal red and white blood cells, indicating no pleocytosis, and normal glucose and protein levels, which ruled out meningitis or encephalitis. *Id.* at 38. Dr. Galletta "[d]oubt[ed]" I.J. had contracted botulism,[6] tetanus,[7] bacteremia[8] or other bacterial infection, or listeria.[9] *Id.* at 40. The consult record by Dr. Galletta listed diagnoses of TM and acute TM. *Id.* at 38.

On 10 August 2013, I.J. was examined by an infectious disease specialist, who ordered a number of tests to rule out several suspected infectious diseases. *Id.* at 40. The infectious disease specialist believed the presence of pathogen gram-positive rods ("GPR") in a portion of

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[2] Transverse Myelitis is inflammation of the spinal cord in which the functional effect of the lesions spans the width of the entire cord at a given level. W.A. Newman Dorland, Dorland's Illustrated Medical Dictionary at 1201 (33rd ed. 2020).

[3] Neuromyelitis Optica is combined, but not usually clinically simultaneous, demyelination of the optic nerve and the spinal cord; it is marked by diminution of vision and possibly blindness, flaccid paralysis of the extremities, and sensory and genitourinary disturbances. *See* Dorland, *supra* note 2, at 1249.

[4] Acute Disseminated Encephalomyelitis is characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination; it occurs most often after an acute viral infection, especially measles, but may occur without a recognizable antecedent. It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. *See* Dorland, *supra* note 2, at 607.

[5] Varicella-zoster virus is human herpesvirus 3. *See* Dorland, *supra* note 2, at 2035.

[6] Botulism is food poisoning with neurotoxicity resulting from the eating of spoiled food contaminated with *Clostridium Bacterium*. *See* Dorland, *supra* note 2, at 238.

[7] Tetanus is an acute infectious disease caused by *Clostridium tetani*, which produces the exotoxins tetanospasmin and tetanolysin; it usually enters the body through a contaminated puncture wound or insect bite. *See* Dorland, *supra* note 2, at 1875.

[8] Bacteremia is the presence of bacteria in the blood. *See* Dorland, *supra* note 2, at 188.

[9] Listeria is a genus of bacteria of the family Listeriaceae, made up of small, coccoid, gram-positive rods that have a tendency to form chains and palisades; they are found in animal feces, on vegetation, and in silage. *See* Dorland, *supra* note 2, at 1052.

the test results represented contamination of the samples not due to bacterial infection. *Id.* The specialist also noted I.J.'s improvement with steroids and IVIG. *Id.*

The follow-up evaluations on 11 August 2013 and 12 August 2013 noted I.J. was continuing to improve with the steroid and IVIG treatments, specifically in upper extremity function. *Id.* at 131. The record states I.J. received a "5 day course of steroids (Solumedrol) and a 5 day course of IVIG," and he had "marked improvement on his upper extremity strength though still not at baseline." *Id.* at 139. The lack of leg movements was "still a concern," although his sensation had "improved markedly since admission." *Id.* The plan following this evaluation was to start a five-day course of plasmapheresis ("PLEX")[10] on 13 August 2013. *Id.*

I.J. was evaluated by a rheumatologist on 13 August 2013 who reviewed all of his blood work and studies. *Id.* at 146. The blood work revealed signs of mildly elevated Anti-Ro but the rheumatologist felt that the level present was not high enough to cause TM. *Id.* at 50. I.J. also had a central line placed and received his first PLEX treatment on the same day. *Id.* at 146.

I.J. continued to show improvement with IVIG, IVMP, and PLEX treatments, but the improvement was limited to his upper extremities. *Id.* at 176. The treating physicians raised concern for a possible anterior spinal artery ("ASA") occlusion. *Id.* at 177. On 17 August 2013 I.J. was examined by an infectious disease specialist, Dr. Louie. *Id.* at 61. Dr. Louie stated I.J. had received a Hepatitis B vaccination[11], and Dr. Louie raised the concern of TM being associated with vaccines. *Id.* Dr. Louie also noted the low probability of I.J. having an infection based on I.J.'s improvement from the steroid and IVIG treatments and all tests being negative for infection. *Id.* The doctor agreed with the plan of evaluating I.J. for possible ASA and recommended a respiratory virus culture to rule out all possible infections as the cause for the symptoms. *Id.*

I.J. received another MRI on 17 August 2013.[12] *Id.* at 10. This MRI was conducted for differential diagnoses between TM and spinal cord infarction. *Id.* Evidence supporting the diagnosis of TM included I.J.'s age, the repeat occurrence, holocord involvement, and cervical location. *Id.* Evidence supporting the diagnosis of spinal cord infarction included "restricted diffusion in portions of lesion, the focal gray matter T-2 bright lesions noted on the current examination as well as the prior examination, and the focal gray matter enhancement in portions of lesions." *Id.* A hematologist noted I.J.'s symptoms were consistent with a vascular event in the spinal cord (embolization or venous thrombosis), highlighted I.J.'s family history of thrombophilia, and recommended thrombophilia studies. *Id.* at 63–65.

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[10] Plasmapheresis is the removal of plasma from withdrawn blood, with re-transfusion of the formed elements into the donor; this may be done for therapeutic purposes. *See* Dorland, *supra* note 2, at 1434.

[11] Dr. Louie wrongly noted that I.J. received a Hepatitis B vaccination in the medical record. *Id.* at 61; Med. Recs. 8-2 at 38. I.J. actually received a DTaP vaccination in preparation for his new job as noted *supra*. Med. Recs. 8-2 at 38.

[12] The medical record states that the MRI was done on 16 August 2013 for a differential diagnosis between spinal cord infarction and transverse myelitis. *Id.* at 10. All parties refer to this MRI as the 17 August 2013 MRI. *See* Mot. for Review at 18; HHS Alexander Expert Report, ECF No. 79-1 ("Alex. Exp. Rep.") at 2 (HHS Expert Alexander's Opinion); Decision at 3. The medical record later refers to this MRI as the 17 August 2013 MRI. *See* Med. Recs. 8-2 at 10.

On 20 August 2013, I.J.'s treating physicians reviewed the 17 August 2013 MRI imaging and interpreted the abnormalities to be "now more concerning for spinal cord infarct[ion] than transverse myelitis." *Id.* at 71. On 21 August 2013, I.J. was examined by a hematologist, Dr. Hymes, who noted I.J. had an "acute onset of paraplegia with angiographic evidence of a spinal artery occlusion," but stated "the findings on the thrombophilia panel can be seen in inflammation, and by themselves would not be responsible for the aggressive thrombotic process as evident here." *Id.* at 76. Dr. Hymes further noted the hematology panel was negative for a "lupus anticoagulant," which, if positive, "would be the most likely explanation of a spinal cord infarction." *Id.* Dr. Hymes stated an embolic lesion "remain[ed] the most likely diagnoses," even though the site of the embolus remained "cryptic." *Id.*

I.J. was also examined on 21 August 2013 by an internist, Dr. Taff, who examined the differential diagnoses of TM and spinal cord infarct based on the most recent MRIs. Medical Records, ECF No. 8-3 ("Med. Recs. 8-3") at 230 (Additional NYU Medical Records). Dr. Taff noted the "[p]atient age, holocord involvement and cervical location favor[ed] transverse myelitis," but a "spinal cord infarct [was] suggested by restricted diffusion in portions of [the] lesion." *Id.* at 230–31. Dr. Taff also raised the concern of I.J.'s immunization record because of the concern TM could happen after Hepatitis B vaccinations. *Id.* at 231. Dr. Taff recommended a CT angiogram for "further evaluation of spinal arterial supply." *Id.*

Dr. Ahn, a physician specializing in spinal cord rehabilitation, provided an opinion regarding I.J.'s spinal cord angiogram results from 22 August 2013.[13] Petitioner's Memorandum in Supp. of Mot. for Review of the Special Master's Dec. Filed on Jan. 4, 2021, ECF No. 118 ("Mot. for Review") at 15–16 (Petitioner's Memorandum in Support of Motion for Review of the Special Master's Decision). Dr. Ahn suggested the inflammatory process as shown in the radiographic studies was associated with TM. *Id.* Dr. Ahn noted the etiology of the findings was unclear and the subacute changes could be related to "an earlier thrombotic event," but the "more extensive distribution of the lesion present on MRI[] could represent passive compressive or active perivascular inflammatory changes arising from the associated cervical spinal pathology swelling." *Id.* Dr. Ahn accepted I.J. to be transferred to the rehabilitation center and noted the admitting diagnosis as "transverse myelitis with C5 tetraplegia, sensory incomplete." Med. Recs. 8-3 at 326.

On 26 August 2013, I.J.'s attending neurologist, Dr. Sanger, opined the ASA blockage at C5 could have been due to spinal cord swelling and provided his clinical opinion of I.J. being diagnosed with TM. *Id.* at 281. He noted in the medical record that I.J. was "found to have transverse myelitis." *Id.* Prior to I.J.'s transfer to the rehabilitation center, his neurologist, Dr. Foo, noted a diagnosis of acute TM, TM, thrombophilia, and tetraplegia. Med. Recs. 8-3 at 286. Dr. Foo also noted an "ASA blockage at C5 level," but felt the "stenosis, occlusion could be due

[13] Petitioner cited this medical record as "Ex. 5 at 41" but the only exhibit in the record labeled as "Ex. 5" is Exhibit 5a. *See* Mot. for Review at 16. This exhibit is only one page in length and is a letter explaining that two pages were omitted from the medical record production filed as Exhibit 5. There is no Exhibit 5 in the record. *See* Medical Records, ECF No. 15 at 1 (Notice of Filing of Medical Records by ECF – Exhibit 5a). Since the exhibit was not submitted by the petitioner, the Court must cite from the Petitioner's Motion for Review.

to cord swelling." *Id.* at 291. I.J.'s immunologist, Dr. Sterling, noted I.J.'s "acute progressive weakness" and stated the diagnosis is "less likely spinal infarct per neuro[logist]." *Id.* at 92. Dr. Sterling also noted "recent vaccinations could be related with transverse myelitis." *Id.* Dr. Sterling recommended another consult with neurology to determine what pre-employment vaccines I.J. received and the dates of the vaccines as they may be associated with the TM diagnosis. *Id.* In I.J.'s discharge summary, Dr. Foo noted that I.J. was improving with the treatment of the steroids and IVIG for TM. *Id.* at 9.

I.J. was discharged but continued to receive rehabilitation for several months in intensive inpatient rehabilitation. Medical Records, ECF No. 22-1 ("Med. Recs. 22-1") at 3–4 (Medical Records from Brandywine Nursing Home). I.J. was first transferred to Brandywine Nursing Home, where he was in therapy for approximately six months. *Id.* He was then transferred to Lindenwood Nursing Facility on 22 August 2014 for continued nursing and rehabilitative care. Medical Records, ECF No. 17-1 ("Med. Recs. 17-1") at 4 (Medical Records from Linden Center for Nursing and Rehabilitation). I.J. was admitted to the Lindenwood facility with a diagnosis of "spinal cord infarction versus transverse myelitis, paraplegia, and thrombophilia." *Id.* I.J. spent seven months at Lindenwood before being discharged on 20 March 2015. *Id.* at 1. His diagnosis at the time of discharge was "unspecified spinal cord diseases." Med. Recs. 17-1 at 380. The record does not contain documentation of I.J.'s current medical or rehabilitative services since his discharge in March 2015. Decision at 8.

II. The Vaccine Petition and Hearing Before the Special Master

Petitioner filed his vaccine petition against the Secretary of Health and Human Services ("respondent") on 21 July 2016. *See* Pet. for Vaccine Compensation, ECF No. 1. Petitioner requested compensation for injuries he suffered from flaccid paraplegia and tetraplegia related to transverse myelitis he allegedly developed after receipt of a Tdap vaccination on 22 July 2013. *See id.* at 1. Respondent filed a response to petitioner's motion for review on 4 March 2021. *See* Respondent's Mem. in Resp. to Pet'r's Mot. for Review, ECF No. 122 ("Resp. to Mot. for Review").

A. Declarations and Testimonies Presented Before the Chief Special Master

1. Petitioner's Testimony

I.J. submitted an affidavit and provided testimony in front of the Chief Special Master at an entitlement hearing. Petitioner's Affidavit, ECF No. 6-1 ("Affidavit") (Declaration of I.J. seeking compensation for injuries sustained after receiving a Tdap vaccination); 2019 Tr. at 7:18–40:14. I.J. stated in the affidavit and at the hearing the only health problems he experienced throughout childhood and adulthood were gallstones and a torn anterior crucial ligament ("ACL"). Affidavit at 2–3; 2019 Tr. at 11:9–12:4. The ACL tear required arthroscopic surgery, and at pre-surgery testing I.J. was declared healthy and cleared for surgery. Affidavit at 2–3; 2019 Tr. at 12:5–12.

I.J. explained he was offered a job as a patient advocate at NYU Medical Center in 2013. Affidavit at 2; 2019 Tr. at 12:13–23. As a prerequisite to employment as a patient advocate, I.J.

had to receive a Tdap vaccination. Affidavit at 2; 2019 Tr. at 13:5–13:13. I.J. received the Tdap vaccination on 22 July 2013. Affidavit at 2; 2019 Tr. at 13:11–13. Approximately two weeks after receiving the Tdap vaccine, I.J. began experiencing various symptoms. Affidavit at 2–3; 2019 Tr. at 14:5–15:11. The symptoms quickly worsened, causing him to walk to NYU Medical Center for evaluation. Affidavit at 2–3; 2019 Tr. at 15:11–17:20. Upon arrival at NYU Medical Center, I.J. was admitted to the emergency room with worsening symptoms, including progressive weakness, numbness, and "needle-like" sensations. 2019 Tr. at 20:9–21:9.

Shortly after admission to the emergency department, I.J. underwent an MRI. *Id.* at 24:5–7. I.J. recalls being fully mobile prior to the MRI, but states he lost all mobility from the neck down immediately following the MRI. *Id.* at 24:8–27:13. I.J. also exhibited urinary retention, requiring catheterization, and difficulty regulating his body temperature. *Id.* at 28:20–30:4. While in the hospital, I.J. received IVIG and plasmapheresis treatments, which led to a regaining of some mobility in his arms. *Id.* at 28:5–15.

Going through rehabilitation after leaving the hospital, I.J. was eventually able to support his own body weight with his arms. *Id.* at 31:19–25. After I.J.'s extended time at Rusk Rehabilitation, he was transferred to Brandywine Nursing Home for additional therapy and rehabilitation. *Id*. at 32:1–3. I.J. spent six months at Brandywine before being transferred to Lindenwood Nursing Facility. Affidavit at 3–4; 2019 Tr. at 33:23–25. I.J. was eventually discharged from Lindenwood but continues physical therapy at Rusk Rehabilitation and through a community access program. 2019 Tr. at 34:22–37:4. I.J. has recovered some strength in his legs and mobility in his arms, but he does not have the same dexterity he had prior to the onset of his injury. *Id.* at 35:20–36:12.

2. Petitioner's Experts

a. Dr. Zamvil, M.D., Ph.D.

Dr. Zamvil, a neuroimmunologist, testified before the Chief Special Master and offered a single expert report. *See* 2019 Tr. at 40:15–160:17; Expert Report of Scott S. Zamvil, M.D., Ph.D., ECF No. 31-1 ("Zamvil Ex. Rep.") (The expert report of petitioner's expert witness, Dr. Zamvil). Dr. Zamvil stated the time frame of I.J.'s vaccination "corresponds to both the expected cellular and humoral response to a vaccination" and opined both that Tdap vaccinations can cause TM generally and the vaccine did specifically cause Petitioner's TM. Zamvil Ex. Rep. at 6–7. Dr. Zamvil described the inflammation criterion set by the Transverse Myelitis Working Group and explained whether he believed "that criterion is met by the evidence in this case." *Id.* at 80:24–82:15 (citing Transverse Myelitis Consortium Working Group, *Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis*, 59 NEUROLOGY 499 (2002), ECF No. 63-4 ("the Working Group")). He addressed the issue of inflammation being established by pleocytosis,[14] elevated immunoglobin G ("IgG") index, or gadolinium[15] enhancement. *Id.* at 81:4–15. Dr. Zamvil noted I.J.'s cerebrospinal fluid[16] ("CSF") analysis was negative for

[14] Pleocytosis is the presence of a greater than normal number of cells in the cerebrospinal fluid. *See* Dorland, *supra* note 2, at 1438.
[15] Gadolinium is a silvery white, malleable, ductile, heavy metal, rare earth element. *See* Dorland, *supra* note 2, at 745.
[16] Cerebrospinal fluid is fluid from the brain and spinal cord. *See* Dorland, *supra* note 2, at 328.

pleocytosis, but he opined this was an insufficient reason to rule out TM as a diagnosis because only fifty-seven percent of patients experiencing TM will exhibit pleocytosis. *Id.* at 81:16–82:21. Dr. Zamvil also agreed I.J. did not have an elevated IgG index or gadolinium enhancement on his initial MRI test performed on 8 August 2013. *Id.* at 81:8–15. The MRI performed on 17 August 2013 revealed inflammation, but a repeat CSF study was not performed. *Id.* at 68:22–69:17. Dr. Zamvil opined if the physicians had repeated the CSF testing, "it's possible and . . . maybe more likely" the repeated CSF would have shown inflammation given "enhancement on the [17 August 2013] MRI in that manner." *Id.* at 69:18–22.

Additionally, Dr. Zamvil opined the "bubble study" did not support spinal cord infarction[17] ("SCI") as a proper diagnosis. *Id.* at 55:13–24. The study did not reveal a right-to-left shunt, and Dr. Zamil opined the lack of a right-to-left shunt is strong evidence against a SCI diagnosis. *Id.* at 56:6–57:3 (testifying the lack of right-to-left shunt "would pretty much eliminate that particular possible etiology if a patient has a stroke"). Dr. Zamvil also opined I.J.'s prolonged "stuttering" onset of symptoms was more consistent with TM than SCI. *Id.* at 60:5–20 ("[H]e had a symptom. He developed another symptom. Then it may have progressed again . . . a stuttering course that occurs for more than six hours is consistent with a myelitis."). I.J. reached nadir at least six hours after his initial onset of symptoms. *Id.* at 57:10–13 ("The time period from onset of symptoms, from the pinch or whatever upper sensory type symptoms in the neck, to maximal deficit here was at least six hours."). Dr. Zamvil stated SCI more commonly presents as "apoplectic" and causes patients to reach nadir within minutes of onset, while TM generally causes patients to reach nadir over the course of several hours. *Id.* at 60:17–20 ("[A]poplectic onset, maximal deficit at onset, is very consistent with an infarct. A stuttering course that occurs for more than six hours is consistent with a myelitis.").

Dr. Zamvil proposed molecular mimicry as a potential mechanism of Tdap causing TM. Zamvil Ex. Rep. at 9 ("Through molecular mimicry, vaccination with TDaP could lead to amplification of pathogenic T cell or B cell (antibody) immune response causing inflammation in the spinal cord."). Dr. Zamvil conducted a BLAST search[18] to find homology between Tetanus toxoid ("TT"), "one of the three component protein antigens in TDaP[,] . . . with human myelin proteins." *Id.* at 10. Dr. Zamvil first evaluated the entire tetanus sequence and identified "[t]wo clear positive examples of homology": "The TT amino acid sequence 264-274 shared 64% (7 of 11) identity with myelin regulatory factor-like protein amino acids 671-681 . . . , and TT sequence 366-375 shared 60% (6 of 10) identity with myelin-associated neurite-outgrowth factor inhibitor amino acids 180-189." *Id.* Dr. Zamvil then focused on "TT amino acid sequence 830-844, . . . [b]ecause TT p830-844, like intact TT, elicits a strong response in TT vaccinated individuals." *Id.* at 10–11. Dr. Zamvil found "[r]emarkably, there was an 83% [sic] (5 of 6 amino acids) between sequence 887-892 and amino acids 151-156 of proteolipid protein (PLP) . . . , the most abundant encephalitogenic protein in myelin tissue." *Id.* at 11. Accordingly, Dr.

[17] Spinal Cord Infarction is the formation of an area of coagulation necrosis in a tissue due to local ischemia resulting from obstruction of circulation to the vessel within the spinal cord. *See* Dorland, *supra* note 2, at 922–23.

[18] BLAST is an acronym for the "Basic Local Alignment Search Tool," a tool which finds regions of similarity between biological sequences. The program compares nucleotide or protein sequences to sequence databases and calculates the statistical significance. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION, https://blast.ncbi.nlm.nih.gov/Blast.cgi (last visited June 9, 2021).

Zamvil concluded "it is plausible that TDaP vaccination elicited T cells from [I.J.] could have responded to a CNS autoantigen like PLP." *Id.*

Dr. Zamvil further reviewed medical literature to support the position "[t]he association of transverse myelitis and Tetanus toxoid (TT)-containing vaccination was clear." *Id.* at 7 ("In a systematic review of the literature, between 1970 and 2009 there were 37 cases of transverse myelitis associated with vaccination, including four that occurred after DTP [(diphtheria–tetanus–pertussis)] (this includes cellular (killed) and acellular vaccines) or DT [(diphtheria–tetanus)].") Dr. Zamvil noted "as transverse myelitis following TDaP is a rare event, one should recognize that it has been challenging for epidemiologists to establish a relative risk." *Id.* (citing Roger Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 CLIN. INFECT. DIS. 1456 (2016)).

b. Dr. Alyssa Watanabe

Dr. Watanabe examined I.J.'s medical record and imaging studies and rendered an opinion on the diagnosis of TM versus stroke. Expert Report, ECF No. 52-1 ("Watanabe Ex. Rep.") at 1 (Dr. Watanabe's expert report concerning Tdap causing I.J.'s TM based on medical imaging tests). Dr. Watanabe testified the CT angiogram I.J. underwent on 8 August 2013 revealed no vascular abnormalities, which did not support a finding of infarct or stroke. 2019 Tr. at 171:12–14, 172:15–22 ("[T]he most common . . . underlying factor in getting a stroke in your spinal cord is having arthrosclerotic disease or some sort of plaque or disease involving your aorta or the arteries leading up."). Dr. Watanabe then discussed the MRI test I.J. underwent on 8 August 2013 MRI. *Id.* at 172:7–10. Dr. Wanatabe agreed with I.J.'s treating physicians' interpretation of the imaging "as compatible with transverse myelitis." *Id.* at 172:14–16 ("[The 8 August 2013 MRI] was interpreted by the radiologist at NYU as compatible with transverse myelitis, and I would have read it the same way."). She noted the 8 August 2013 scan showed no enhancement. *Id.* at 218:16–19.

Dr. Watanabe noted I.J.'s 17 August 2013 MRI showed gadolinium enhancement consistent with an inflammatory process. *Id.* at 178:10–19. Dr. Watanabe opined "the patchy enhancement throughout the area of the spinal cord" in the 17 August 2013 MRI "indicates that there was a blood-brain barrier breakdown, inflammation, and development of necrosis and cell death, which can be part of what occurs in transverse myelitis." *Id.* at 193:14–22. Dr. Wanatabe noticed the "contrast enhancement" seen in the 17 August 2013 MRI but not in the 8 August MRI was "not unexpected," due to the earlier MRI being performed "so early in the onset of [I.J.'s] disease." *Id.* at 177:23–178:6 ("In the literature, in a series of cases where patients were imaged within 14 hours of onset, 80 percent of those patients did not show anything lighting up . . . in that very early phase."). Dr. Watanabe also pointed out the "abnormal cord signal in the posterior part of the cord" in the 17 August 2013 MRI does not support a SCI diagnosis, because "if the patient were to have had an anterior spinal artery infarct, you'd expect the infarct on the spinal cord images to be seen in the distribution pattern of the anterior spinal artery itself." *Id.* at 179:8–22. Dr. Wanatabe cited two additional pieces of support for the 17 August 2013 MRI being "more likely than not more compatible with acute transverse myelitis than an infarct of the anterior spinal artery": "The lesion [in MRI imaging] extends into the white matter, and it's not isolated just to the gray matter tracts, which is another hallmark of myelitis rather than an

anterior spinal artery infarct"; *Id.* at 183:14–25; and "th[e] very extensive holocord experience . . . [as] the white stuff almost entirely replacing the cord, except . . . some of the perimeter, . . . are all signs that are indicative, more likely than not, of a transverse myelitis rather than an anterior spinal artery infarct." *Id.* at 184:1–7.

Dr. Watanabe noted the "mild diffusion restriction" shown by the 17 August 2013 MRI—"something that can be seen with both [TM and SCI]"—"led to a consultation with the stroke team, who then recommended [an] angiogram [test]." *Id.* at 184:16–21. Dr. Watanabe testified the angiogram did not reveal evidence of a blood clot or a "cutoff." *Id.* at 185:20–23 ("[T]he neuroradiologist who performed and interpreted this angiogram never said "cutoff," and he never said he saw a clot."), 188:15–16 ("[W]hat the angiogram shows is that we don't see a clot in the vessel that may have caused a stroke."). Nevertheless, she acknowledged the possibility "that there could have been a clot that could have disappeared, and now the vessel had recanalized." *Id*. at 188:2–6.

Dr. Watanabe acknowledged I.J.'s symptoms did not strictly meet all the Working Group Diagnostic criteria. *Id.* at 209:25–210:10. Dr. Watanabe, however, disagreed the missing of certain criterion meant "one cannot reach a diagnosis of TM." *Id.* at 210:13–18. Dr. Watanabe explained "in a clinical setting [doctors] make their own judgments, and [they are] not restricted by this paper [of the Working Group]." *Id.* at 210:19–20.

c. Dr. Mark Levin

Dr. Levin, a hematologist, offered an expert report and testimony stating I.J.'s overall hematologic condition was insufficient to support a SCI diagnosis. 2019 Tr. at 236:3–17; Expert Report, ECF No. 68-1 ("Levin Ex. Rep.") (Dr. Levin's report concluding a diagnosis of SCI was not supported). Dr. Levin addressed I.J.'s family history of venous thromboembolism ("VTE"),[19] and whether it was significant for diagnostic purposes. Levin Ex. Rep. at 2–3. Dr. Levin noted, while there are a number of questions in the normal medical practice a doctor should ask to understand if there is a genetic component, "[a]side from the mention of a history of pulmonary embolism in two [of I.J.'s] relatives, there really was nothing else that [treating physicians] looked into, tried to understand if there is a genetic component." 2019 Tr. at 238:12–20 (Dr. Levin testifying "when you look at the family history, you really need specifics, what age and what circumstances. For example, we're always trained to ask questions . . . [(a long list of questions are omitted)]. None of this was available in the record."). Dr. Levin opined the two factors respondent's expert testified as abnormal—Factor VIII and protein S laboratory data—do not indicate a genetic condition. 2019 Tr. at 239:16–19; Levin Ex. Rep. at 4.

Dr. Levin testified I.J.'s elevated factor VIII level is "the effect of inflammation that happened from myelitis." 2019 Tr. at 240:15–24. Dr. Levin opined "findings of inflammation in the blood are the cause of the elevated Factor VIII level and not the opposite." Levin Ex. Rep. at 4. Dr. Levin further noted "[t]he elevated Factor VIII is completely consistent with a diagnosis of transverse myelitis," and "even had [respondent's expert] been correct that a spinal

[19] Venous Thromboembolism is obstruction of a vein with thrombotic material carried by the bloodstream from the site of origin to plug another vessel. *See* Dorland, *supra* note 2, at 1892, 2016.

cord infarction occurred, it would have most likely have been caused by the vaccine-caused inflammation." *Id.*

3. Respondent's Expert – Dr. David Alexander

Dr. Alexander, a neurologist and Respondent's sole expert provided testimony with three reports. 2019 Tr. at 291–389; Expert Report, ECF No. 41-1 ("Alexander Ex. Rep. 1") (Dr. Alexander's first expert report); Expert Report, ECF No. 79-1 ("Alexander Ex. Rep. 2") (Dr. Alexander's second expert report); Expert Report, ECF No. 107-1 ("Alexander Ex. Rep. 3") (Dr. Alexander's third expert report). Dr. Alexander opined I.J.'s Tdap vaccine "is not related to his injury, which . . . is a spinal cord infarction." 2019 Tr. at 299:16–25.

Dr. Alexander's basis for his opinion that I.J. does not have TM is "[I.J.] doesn't fit . . . the Transverse Myelitis Consortium Working Group definition." 2019 Tr. at 300:5–12. In particular, Dr. Alexander found I.J. "didn't have any evidence of inflammation," as "[t]here was no [g]adolinium enhancement on his initial MRI scan, and he didn't have a CSF that showed any inflammatory pleocytosis," while "[b]oth of those are criteria . . . for [TM] diagnosis." *Id.* at 300:13–17. Dr. Alexander further noticed "[I.J.'s] abrupt onset of symptoms that then evolved over a bit of time . . . is much more consistent with acute ischemic stroke to the spinal cord." *Id.* at 300:18–21. Dr. Alexander opined "[t]he imaging shows very characteristic findings of spinal cord infarction." *Id.* at 300:23–24.

Regarding I.J's MRI studies, Dr. Alexander testified the first MRI on 8 August 2013 shows "the typical pencil-shaped lesion that you see in spinal cord infarction, ventral cord and preservation of the posterior elements there on the sagittal scan." *Id.* at 317:21–24. Dr. Alexander opined, if I.J. had TM, "in an MRI scan obtained hours after onset of symptoms," one would "expect to see more involvement of the cord rather than a simple stripes," and "[i]t could be the whole cord . . . , and you would expect to see enhancement." *Id.* at 318:4–14. Dr. Alexander concluded "even on this [8 August 2013 MRI] scan I would say that this is entirely consistent with acute spinal cord infarction." *Id.* at 317:11–12. Dr. Alexander acknowledged, if the treating physicians had suspected SCI on I.J.'s admission, they would have asked for a diffusion-weighted imaging ("DWI")[20] sequence for the 8 August 2013 MRI imaging, but the doctors did not. *Id.* at 363:12–16. Dr. Alexander explained "the gold standard for acute stroke in the brain or the spinal cord at this point and day and age [of I.J.'s onset] is diffusion-weighted imaging," which is "the most important single test [doctors] do when looking at acute stroke," and it has to be performed shortly after the onset of symptoms. *Id.* at 307:11–18, 308:3–9. ("That DWI positivity comes on and peaks . . . relatively soon and decays after that. So it's not a long-lasting—it's a measure of acute infarction and, in the brain, the most important single test we do when looking at acute stroke.").

[20] DWI is a form of magnetic resonance imaging based upon measuring the random Brownian motion of water molecules within a voxel tissue. Highly cellular tissues or those with cellular swelling exhibit lower diffusion coefficients and diffusion is particularly useful in characterization of cerebral ischemia. Ayush Goel et al, *Diffusion-weighted Imaging*, RADIOPAEDIA (last visited June 10, 2021), https://radiopaedia.org/articles/diffusion-weighted-imaging-2?lang=us.

Dr. Alexander then reviewed the findings from the second MRI test I.J. underwent on 17 August 2013. *Id.* at 320:23–321:6. Dr. Alexander acknowledged the MRI imaging "could be [indicative of] transverse myelitis." *Id.* at 323:19–23 (When asked "[c]an anything on this [MRI] scan be indicative of transverse myelitis," Dr. Alexander testified "I couldn't tell exactly what that is. It could be transverse myelitis."). Dr. Alexander commented Dr. Watanabe's opinion of "an area of involvement of some kind of the dorsal columns" as "not being noteworthy," and "the treating physicians did not comment on this dorsal column because the predominant finding was that of ventral cord involvement." *Id.* at 321:15–322:18. Dr. Alexander acknowledged, "[a]lthough the predominant infarction in [I.J.] is in the distribution of the ASA [(anterior spinal arteries)], I agree there is also ischemia in the posterior PSA [(posterior spinal arteries)] distribution." Alexander Ex. Rep. 3 at 5. Dr. Alexander opined "this finding is not uncommon, and supports, rather than undermines, the idea that [I.J.] had a SCI and not TM," because both the anterior and posterior spinal arteries are fed by the radiculomedullary artery.[21] *Id.* Dr. Alexander further noticed "the sharp medial edge of the signal intensity brightness" supported the reading of SCI, because "TM would not respect the midline . . . , whereas a spinal cord infarction would have a sharp demarcation corresponding to a vascular territory." *Id.* at 6–7.

Dr. Alexander also addressed the 21 August 2013 Angiogram, which he opined as supporting his conclusion of a SCI diagnosis. *See* Alexander Ex. Rep. 3 at 2 ("The correct interpretation is that this angiogram is entirely consistent with an acute stroke thirteen days ago."). Dr. Alexander explained the absence of blood clots on the angiogram was not conclusive because clots often dissolve and leave behind residual arteriole narrowing. *Id.* ("One would not expect to find embolus or thrombus thirteen days after an infarct."), *see also* 2019 Tr. at 333:25–334:8. Dr. Alexander agreed with Dr. Watanabe that the angiogram does not show a cutoff, but Dr. Alexander opined "mini-strokes are not 100 percent occlusions," and "[on] 11 days post-event . . . [doctors] wouldn't expect . . . to see a residual cutoff or clot in the vessel." *Id.* at 335:9–21.

Dr. Alexander disagreed with Dr. Levin's testimony that I.J.'s elevated Factor VIII level "was a systemic change in that 24 hours based on inflammation within the cord of myelitis." *Id.* at 343:9–13. Dr. Alexander opined, due to the small amount of tissue involved in TM, the inflammation cannot trigger a systematic reaction like elevation in Factor VIII level. *Id.* at 343:14–19. Dr. Alexander found "there's no local inflammation," and "with no local reaction," he found "it hard to believe . . . a small degree of myelitis . . . create[ed] a systemic response with changes in . . . factor levels." *Id.* at 343:20–344:2. Dr. Alexander noted the elevated Factor VIII level could be to due to I.J. being "a sick ICU guy" who was "developing infections, possible aspiration pneumonia, being treated with antibiotics, and having hypotension." *Id.* at 344:3–10.

Dr. Alexander opined the sudden onset time frame of I.J.'s symptom does not support a diagnosis of TM. *Id.* at 372:9–23 ("It's a typical course for a gradually progressive inflammation that's been building up over . . . two weeks or so."). Nevertheless, Dr. Alexander acknowledged "timeline in terms of maximal deficit" noted in the Working Group is "between four hours and 21 days," which is "what happened in [I.J.'s] case." *Id.* at 375:8–14. Dr. Alexander also noted I.J.'s improvements with treatments was not indicative of him having TM, because there is no

[21] The radiculomedullary artery is an artery of the spinal cord. *See* Dorland, *supra* note 2, at 1547.

valid scientific evidence supporting the treatments I.J. received actually work for TM, and I.J.'s improvements, if there are any, are "spontaneous improvement in the sensory symptoms . . . [that] indicate more spinal cord infarction." *Id.* at 111:17–112:14.

B. The Special Master's Decision Denying Compensation

On 4 January 2021, Chief Special Master Corcoran issued his decision denying petitioner's claim and denying compensation, concluding although "[p]etitioner has preponderantly established that he likely experienced TM, prevailing over [r]espondent's proposed alternative diagnosis of a spinal cord infarction," "insufficient preponderant evidence offered in this case stands for [p]etitioner's contention that the Tdap vaccine can cause TM, or that it did so in this case." *J.*, No. 16-864, ECF No. 125, at 2 (emphasis omitted).

The Chief Special Master began the analysis by determining whether petitioner's injury was likely either TM or a spinal cord infarction. *Id.* at 35. As petitioner's causal theory was dependent on the establishment of his injury as TM, and petitioner did not allege a spinal cord infarction could be vaccine-caused, "a determination that [a spinal cord infarction] best characterized his injury would be fatal to his claim." *Id.* The Chief Special Master found "this issue is close, with the evidence largely in equipoise," as "both sides offered credible, reliably-bulwarked points for their respective positions, supported in turn by fair and persuasive expert testimony," and "the medical record is ultimately equivocal on the matter." *Id.* at 35–36. While "it is not [the Chief Special Master's] function . . . to propose a 'correct' diagnosis," the Chief Special Master carried out his duty to "weigh whether the evidence preponderantly supports one conclusion over another." *Id.* The Chief Special Master "found preponderant evidence has been offered to establish that [p]etitioner more likely than not suffered from TM" based on the following fact findings: "Petitioner . . . experienced sensory, motor, and autonomic dysfunction consistent with TM"; a number of other etiologies such as "connective tissue disease, infectious disease, abnormal void flows, and spinal radiation . . . optic neuritis and MS" were absent or eliminated; "[t]he progression of [p]etitioner's symptoms over the course of approximately eight or nine hours satisfied the Working Group's proposed diagnostic criteria and further distinguished [p]etitioner's course from that which is typical of spinal cord infarction"; "there is treater support for his proposed diagnosis"; and "a review of the medical record beyond [petitioner's] initial onset does not suggest, based on the accumulation of additional information over time, that treaters later abandoned TM as an explanation." *Id.* at 36.

The Chief Special Master next reviewed relevant case law regarding vaccine causality of TM. The Chief Special Master noted "a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (2005): '(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury'" to establish entitlement of compensation for a non-table claim. *Id.* at 28. The Chief Special Master further noted "several more recent, well-reasoned decisions have found that petitioners failed in their effort to establish that the flu vaccine 'can cause' TM, as required by the first *Althen* prong." *Id.* at 37. While acknowledging "such determinations are somewhat less on point given the different vaccine at issue," the Chief Special Master found the cases "cast light on identifying

deficiencies in the reasonings" of causality. *Id.* In *Pearson*, an adult petitioner alleged his receipt of the flu vaccine precipitated the onset on TM within three months, relying on molecular mimicry and Agmon-Levin's review of post-vaccine TM cases to support causation. *Id.* (citing *Pearson v. Sec'y of Health & Human Servs.*, No. 16-09V, 2019 WL 3852633, at *3–4, *6–7 (Fed. Cl. Spec. Mstr. July 31, 2019)). The respondent in *Forrest*, another case of a petitioner alleging the flu vaccine caused TM, offered Baxter to undermine causation and argue "the very large-scale study saw no increased incidence of TM after administration of the flu vaccine." *Id.* at 38 (citing *Forrest v. Sec'y of Health and Human Servs.*, No. 14-1046, 2019 WL 925495, *5 (Fed. Cl. Spec. Mstr. Jan. 29, 2019)). Although denying compensation based on "the short onset timeframe and its inconsistency with the casual theory," the special master in *Forrest* "took special note of Baxter, observing the extent to which the study undermined the claimant's case (while acknowledging the 'general rule' that petitioners are not required to submit affirmative epidemiologic evidence as part of their *prima facie* case)." *Id.* (citing *Forrest*, 2019WL 925485, at *5).

With this background, the Chief Special Master considered petitioner's *Althen* prong one showing of whether Tdap vaccine can cause TM. *Id*. at 38. The Chief Special Master first noted, "[a]s a threshold matter," "[p]etitioner incorrectly maintains that 'reliable scientific evidence' is not required to meet his preponderant burden." *Id*. (emphasis omitted). According to the Chief Special Master, while "no particular class of evidence (i.e. medical literature; research studies; expert reports; peer-reviewed articles; etc.) need be offered with the overall obligation of Program petitioners to offer a reliable theory, . . . [i]f certain individual components of evidence critical to a theory's success are not themselves reliable, that finding reasonably impacts the overall theory's evidentiary preponderance." *Id.* (citing *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994)). The Chief Special Master further pointed out petitioner "erroneously suggest[ed] a theory's mere plausibility is enough to meet the preponderant standard—a contention that the Federal Circuit clearly rejected in the recent *Boatmon* decision." *Id.* at 38–39 (citing *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019)).

The Chief Special Master found "several deficiencies" in petitioner's causation theory. *Id.* at 39. First, the Chief Special Master stated "scientific evidence not previously available when [previous Tdap cases] were decided," the 2017 Baxter study, failed to serve in plaintiff's favor. *Id.* The Chief Special Master characterized Baxter as "a large-scale, comprehensive epidemiological study aimed at examining the risk of demyelinating event following vaccination . . . within a field of nearly 64 million vaccinations (including almost six million Tdap recipients) derived from data maintained by the Vaccine Safety Datalink." *Id.* (citing Baxter at 1456–57) (emphasis omitted). Baxter reported only seven cases of TM between 5-28 days post-vaccination—the very timeframe applicable to petitioner's claim—and "concluded that there was no reliably-demonstrated association between vaccination and the subsequent development of TM." *Id.* (citing Baxter at 1456–57, 1561 ("In conclusion, TM and ADEM are rarely, if ever, associated with vaccines.")). The Chief Special Master acknowledged, "[a]lthough it is unquestionably the case that Vaccine Program litigants are not required to offer epidemiological evidence to prevail, special masters may take note of its existence and consider it when determining if a claimant has met his burden of proof." *Id.* (citing *Palattao v. Sec'y of Health & Human Servs.*, No. 13-591V, 2019 WL 989380, at *37 (Fed. Cl. Spec. Mstr. Feb. 4, 2019))

(emphasis omitted). Accordingly, the Chief Special Master "[took] Baxter into account . . . and [found] that it greatly damages Petitioner's causation theory." *Id.* The Chief Special Master further noted, although petitioner's expert Dr. Zamvil "expressly relied on the Baxter article to support an association between TM and receipt of the Tdap vaccine," "[Dr. Zamvil's references to Baxter] essentially ignored what is so glaringly unfavorable about them." *Id.* at 39–40.

The second deficiency the Chief Special Master identified in petitioner's causation theory was petitioner's reliance on molecular mimicry. *Id.* at 40–41. The Chief Special Master first found "prior decisions like *Raymo*, *Roberts*, and *Helman*," cases where petitioners successfully relied on molecular mimicry to obtain compensation for TM caused by the Tdap vaccine, were not applicable here because the cases are "limited by other specific aspects of their respective holdings, or diminished by more recent determinations involving the same causal theories producing TM." *Id.* at 40. According to the Chief Special Master, the special master in *Raymo* determined "in acute TM 'homology has not been demonstrated between any suspected precipitating agent and the spinal cord nerve sheaths or axons,'" and the *Raymo* special master "based her liability determination on the finding that the theory of bystander activation—a mechanism not proposed by Petitioner's experts in this case—was also a reasonable causal explanation under the circumstances." *Id.* (citing *Raymo v. Sec'y of Health & Human Servs.*, 11-654V, 2014 WL 1092274, at *18, *20 (Fed. Cl. Spec. Mstr. Feb. 24, 2014)). The Chief Special Master stated the special master in *Roberts* "acknowledged that petitioners' theory was supported by an expert opinion but included no further analysis to explain why the theory was persuasive." *Id.* (citing *Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at *6 (Fed. Cl. Spec. Mstr. Aug. 29, 2013)) (emphasis omitted). And in *Helman*, "only two sentences of the special master's analysis in total are dedicated at all to the first *Althen* prong," with "[n]o analysis explain[ing] how the Tdap vaccine can cause TM, thus greatly limiting the persuasive quality of such a determination." *Id.* (citing *Helman v. Sec'y of Health & Human Servs.*, No. 10-813V, 2012 WL 1607142 at *3 (Fed. Cl. Spec. Mstr. Apr. 5, 2012)).

The Chief Special Master next specifically addressed the shortcomings of petitioner's reliance on molecular mimicry in the present case. *Id.* at 40–41. Petitioners' relying on molecular mimicry to establish causation "must demonstrate . . . that it likely does link the vaccine in question to the relevant injury," and the Chief Special Master concluded "[n]o such showing was made in this matter." *Id.* at 41 (citing *Yalacki v. Sec'y of Health & Human Servs.*, No. 14-278V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd*, 146 Fed. Cl. 80 (2019)). The Chief Special Master found "merely demonstrating some homology between vaccine components and relevant self-structures based on computer database searches does not carry the day." *Id.* (citing *Pek v. Sec'y of Health & Human Servs.*, No. 16-736V, 2020 WL 1062959, at *16 (Fed. Cl. Spec. Mstr. Jan. 31, 2020)). The Chief Special Master further noted "Dr. Zamvil's assertions about the role the vaccine's alum adjuvant could play in activation of an aberrant innate response were even less reliable or persuasive," as "he has not shown, nor offered evidence in addition to his testimony, that reliably suggests or establishes that vaccines containing an aluminum adjuvant can, independent of anything else, cause a pathologic response not otherwise shown to be vaccine-attributable." *Id.* (emphasis omitted).

The Chief Special Master also considered the case reports offered by petitioner and found them "of limited probative value—and not just for the reason that case reports generally are not

given significant weight when deciding Program cases, since they do not establish causation *per se*." *Id.* (citing *Knorr v. Sec'y of Health & Human Servs.*, No. 15-1169V, 2018 WL 6991548, at *30 (Fed. Cl. Spec. Mstr. Dec. 7, 2018)). The Riel-Romeo case report, as noted by the Chief Special Master, "not only involved a young child rather than adult like [petitioner], but also acknowledged that its observation of an association could simply be coincidental." *Id.* at 42 (citing Riel-Romero at 690). Agmon-Levin "provided only four instances of association," and *Pearson* already questioned "the weight this piece of literature should receive overall." *Id.* (citing *Pearson*, 2019 WL 3852633, at *14). Moreover, other articles such as "Pidcock and Gregg emphasize that the documented reports of post-vaccination TM could be coincidental, and neither article claims to establish a causal relationship between vaccination and the subsequent development of TM." *Id.* The Chief Special Master concluded: "[t]hese case reports overall had some evidentiary value, and I have taken them into account . . . [b]ut they are not enough to meet the preponderant burden, especially given the far more comprehensive, contrary evidence provided by Baxter." *Id.*

After concluding petitioner's claim failed to meet the first *Althen* prong—whether the Tdap vaccine can cause TM—and therefore "cannot succeed," the Chief Special Master went on to discuss *Althen* prongs two and three "for purposes of completion of [his] overall analysis." *Id.* The Chief Special Master found "an absence of evidence" to "conclude that the Tdap vaccine likely produced [p]etitioner's TM," and therefore found petitioner failed to establish the second *Althen* prong. *Id.* The Chief Special Master first noted "there was hardly any testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation—a telltale sign confirming the presence of the autoimmune process that [p]etitioner's causation theory proposes would have been instigated by the Tdap vaccine." *Id.* at 42–43. Additionally, "[t]here was . . . no evidence of any autoantibodies that might arguably be associated with the asserted TM cross-reaction," and "no treaters ever proposed that [p]etitioner's injury, however defined, was likely caused by his prior Tdap vaccine." *Id.* at 43. The Chief Special Master also observed the existence of a pre-onset intercurrent respiratory infection in petitioner's medical record and noted "such an infection has in other cases been held to possibly explain various demyelinating conditions." *Id.* (citing *Deshler v. Sec'y of Health & Human Servs.*, No. 16-1070V, 2020 WL 4593162, at *18). The Chief Special Master concluded this alternative explanation, though not dispositive, "undermined somewhat [p]etitioner's claim" as "additional evidence that was not fully explained or distinguished by [p]etitioner." *Id.* Although the Chief Special Master was not persuaded that petitioner had established by a preponderance of the evidence the Tdap vaccine caused petitioner's TM, he nevertheless found "the record and evidence offered in this matter does support the conclusion that [p]etitioner's TM occurred in a medically acceptable timeframe, consistent with his causation theory." *Id.* (citation omitted). "But because [p]etitioner's causation theory in this case was not sufficiently supported with preponderant evidence, the consistency of the onset timing in this case with [p]etitioner's theory does not aid [p]etitioner." *Id.*

III. Petitioner's Motion for Review and Respondent's Arguments

On 3 February 2021, petitioner filed a motion for review of the Chief Special Master's decision. *See* Mot. for Review. Petitioner argues "the [Chief] Special Master's holdings [on whether petitioner met *Althen* prong one] were arbitrary and capricious, constituted an abuse of

discretion, and were contrary to law," and "the [Chief] Special Master thereby heightened [p]etitioner's burden of proof, contrary to law." *Id.* at 2. Petitioner further argues the Chief Special Master's decision on the second *Althen* prong "was internally inconsistent, and thus contrary to law, and unsupported by the facts, and thus arbitrary and capricious." *Id.*

A. Petitioner's Objection 1 Regarding the Special Master's *Althen* Prong One Decision

Petitioner's Objection 1 is:

> Given the specificity of the demonstrated homologies between tetanus toxoid constituents of the vaccine and myelin components of the central nervous system, as well as the proximity of the time frame from vaccination to onset of the transverse myelitis (supporting evidence from *Althen* Prong 3, which was deemed to have been proven), the Special Master's holding that Petitioner had failed to establish by a preponderance *Althen* Prong 1 (a "can it cause" medical theory causally connecting the vaccination and the injury) due largely to the Special Master's consideration of an epidemiological study that simply did not rule out causation between vaccination and the rare incidence of acute transverse myelitis, was arbitrary and capricious, an abuse of discretion, contrary to law and violative of due process of law.
>
> Furthermore, the Special Master thereby improperly heightened the burden of proof required of Petitioner, contrary to law, in particular by requiring an improper and impossible to reach level of specificity in connection with Petitioner's showing of the well-established theory of molecular mimicry.

Mot. for Review at 28.

Petitioner objects to the Chief Special Master's reliance on the Baxter study as "greatly damag[ing] [p]etitioner's medical theory," arguing "[t]he elevation of this particular epidemiological study to a case-breaking status is arbitrary and capricious, an abuse of discretion, and contrary to law." *Id.* Petitioner contends "the absence of expert testimony on this issue [of epidemiology] or any meaningful discussion of [Baxter's] significance in the hearing or virtually anywhere else in the record . . . constitutes a violation of due process." *Id.* at 28–29. Although the Baxter study was offered by petitioner, petitioner emphasizes it has "statistical limitations" and is "of little significance in the rare case of Tdap-induced TM." *Id.* at 29. Petitioner relies on Baxter "not for its statistical epidemiology and conclusions," "but for the data it reported . . . to show that while TM is exceedingly rare, there were 7 instances shown in which TM occurred after Tdap vaccination within the relevant time frame." *Id.* at 31.

Petitioner compares this case to a prior case remanding a decision by the Chief Special Master, *Bender v. Sec'y of Health & Human Servs.*, in which the Court of Federal Claims noted

"the Baxter study did not play a major role in [the Chief Special Master's] determination . . . and the [Chief] Special Master specifically acknowledged that no epidemiologists had been offered as experts." *Id.* at 29 (citing *Bender v. Sec'y of Health & Human Servs*., 138 Fed. Cl. 197 (2018)). In *Bender*, petitioner notes, the Chief Special Master "acknowledged that Baxter was not a 'randomized' study and therefore could not be cited as definite proof that the vaccines at issue could never be associated with the TM in the studied time periods." *Id.* (citing *Bender*, 2018 WL 3679637 at *17).

Petitioner further argues the Chief Special Master unduly heightened petitioner's burden for the specificity "required upon a showing of the well-established theory of molecular mimicry." *Id.* at 32. According to petitioner, "greater specificity than a high degree of homology to myelin components of the central nervous system ("CNS") is not required in the Vaccine Program" to establish the first *Althen* prong, and "[t]o hold otherwise is to unduly raise the burden to be met by petitioners and impair the use of circumstantial evidence envisioned by the Program's requirement of preponderant proof." *Id.* (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325–26 (Fed. Cir. 2006)). Petitioner urges the Court to consider current case law, in which "the special master found BLAST searches (such as those conducted by Dr. Zamvil in the case at bar) reveal[ing] amino acid homologies between antigen components of the HPV vaccine Gardasil and [myelin components of the CNS]" were sufficient to establish "the proffered theory of molecular mimicry." *Id.* at 33 (citing *White v. Sec'y of Health & Human Servs.*, 15-1521V, 2019 WL 7563239 at *21–22 (Dec. 19, 2019)).

Petitioner also argues the Chief Special Master's "post-hoc devaluation of the causal role of molecular mimicry is contrary to the long line of medical literature . . . and case law . . . that supports this well-established theory in the context of vaccines containing tetanus toxoid." *Id.* at 35 (citing *Raymo v. Sec'y of Health & Human Servs.*, No. 11-0654V, 2014 WL 1092274, at *19 (Fed. Cl. Spec. Mstr. Feb. 24, 2014); *Roberts v. Sec'y of Health and Human Servs.*, No. 09-427V, 2013 WL 5314698 (Fed. Cl. Spec. Mstr. Aug. 29, 2013); *Helman v. Sec'y of Health and Human Servs.*, No. 10-813V, 2012 WL 1607142 (Fed. Cl. Spec. Mstr. Apr. 5, 2012); *Hargrove ex rel. Wise v. Sec'y of Health & Human Servs.*, No. 05-694V, 2009 WL 1220986 (Fed. Cl. Spec. Mstr. Apr. 14, 2009); *Bowes v. Sec'y of Health & Human Servs.*, No. 01-481V, 2006 WL 2849816 (Fed. Cl. Spec. Mstr. Sep. 8, 2006)). Petitioner contends the Chief Special Master "essentially required a showing of a specific biological mechanism that cannot be proven" and amounts to "unreachable, unrealistic level of evidence." *Id.* at 36. According to petitioner, "[w]hether a case is analyzed under *Althen* or the 'Can it cause?' formulation, petitioners are not required to establish identification and proof of specific biological mechanisms, as the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Id.* (citing *Raymo*, 2014 WL 1092274, at *12 (quoting *Althen*, 418 F.3d at 1280)) (some internal quotation marks omitted). Petitioner thus argues the Chief Special Master's approach to petitioner's molecular mimicry argument is "contrary to law." *Id.*

In response to petitioner's Baxter arguments, respondent argues "the Chief Special Master is required to take into consideration all of the 'relevant and reliable' evidence presented," rather than "only those parts of the [Baxter] study [(e.g., the data)] that petitioner believes were worth noting." Resp. to Mot. for Review at 8 (citing Vaccine Rule 8(b)(1))

(emphasis omitted). Respondent contends the special master "appropriately weighed the Baxter study" because he "considered all of the evidence and made findings based on the record that are not 'wholly implausible.'" *Id.* at 8–9 (citing *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (findings of fact must be upheld if they are "based on evidence in the record that [is] not wholly implausible")). Respondent further argues the Chief Special Master did not improperly heighten petitioner's burden of proof by giving the Baxter study greater weight than the other evidence offered by petitioner, as the Chief Special Master considered all of the other evidence presented, including the case reports, in determining that petitioner had failed to provide sufficient evidence to meet *Althen* prong one. *Id.* at 12–13. Additionally, as the Baxter study was offered by petitioner's expert and was repeatedly discussed at the hearing, "the fact that petitioner repeatedly failed to develop testimony from Dr. Zamvil that was more favorable to his position does not mean that petitioner was prevented from doing so in violation of his due process rights." *Id.* at 14.

In response to petitioner's argument the Chief Special Master improperly heightened petitioner's burden of proof with respect to molecular mimicry, respondent argues a determination by the Chief Special Master that "molecular mimicry 'likely does link the vaccine in question to the relevant injury' . . . is necessary to prevail on a causation-in-fact claim." *Id.* at 15 (citing *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1360 (Fed. Cir. 2013) (quoting *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"))) (emphasis omitted). Respondent notes Dr. Zamvil "could not identify any studies concluding that Tdap can cause TM via [Dr. Zamvil's] proposed mechanism," and Dr. Zamvil's BLAST test, as noted by the Chief Special Master, is "clearly case-oriented, and is not equivalent to lab or clinical research that an expert might perform and/or rely upon for an opinion." *Id.* (internal quotation marks omitted). Respondent opines the Special Master did not raise petitioner's burden of proof; to the contrary, petitioner simply failed the preponderance standard by providing evidence that "fell far short of the mark." *Id.* at 16.

B. Petitioner's Objection 2 Regarding the Special Master's *Althen* Prong Two Decision

Petitioner's Objection 2 is:

> The Special Master's holding that Petitioner had failed to establish *Althen* Prong 2 ("did it cause" evidence) was rendered *irrational* by its internal inconsistency with his threshold determination that Petitioner had established that his injuries included acute transverse myelitis.
>
> Additionally, the Special Master's interpretation of the medical record regarding inflammation and other signs of TM was arbitrary and capricious.

Mot. for Review at 36 (emphasis in original).

Petitioner objects to the Chief Special Master's reliance "upon a purported absence of inflammation as undermining the diagnosis of TM." *Id.* at 37. Petitioner argues he has addressed "the question of inflammation" in several ways, including by providing statements from petitioner's expert, Dr. Watanabe. *Id.* at 37–38.

Petitioner also argues the Chief Special Master's *Althen* prong two decision suffers from a conflict "between the [Chief] Special Master's determination that TM had been established as threshold issue and his later conclusion that TM was not established for purposes of satisfying *Althen* prong 2." *Id.* at 39. Petitioner opines the special master had "already resolved the specific issue of the significance of inflammation in connection with his threshold determination" by finding "[p]etitioner successfully established *either* that certain of the criteria [of the TM Working Group] (for example, proof of inflammation) had not completely been eliminated, or more generally that a TM diagnosis should not be held to the literal standard set by the criteria." *Id.* (internal citation and quotation marks omitted). Petitioner thus contends "[such] an internal inconsistency, . . . [which led to] an entire category of proof (*Althen* prong 2) [being] deemed non-preponderant, is contrary to law and requires reversal." *Id.*

In its response to petitioner's *Althen* prong two arguments, respondent notes "because the Chief Special Master found that petitioner did not satisfy *Althen* prong one, he was under no obligation to even address petitioner's evidence, or the lack thereof, under the other *Althen* prongs." *Id.* at 18 (citing *W.C.*, 704 F.3d at 1358 (special master was not required to analyze evidence under *Althen* prong one, where the court already determined a petitioner had failed to meet preponderance standard under *Althen* prongs two and three)). Regarding petitioner's allegation the Chief Special Master's *Althen* prong two decision suffers internal inconsistency, respondent argues "[t]he Chief Special Master's finding that petitioner had TM most certainly does not equate to a finding that petitioner's TM *was caused by* his vaccination." *Id.* at 18–19 (emphasis in original). Respondent maintains petitioner's disagreement with the Chief Special Master's "interpretation of the medical record regarding inflammation and other signs of TM" is "not justification to overturn the Chief Special Master's well-reasoned finding" that there was "insufficient support in the record for the conclusion that the Tdap vaccine could have caused petitioner's TM." *Id.* at 19–20.

The Court held oral argument on petitioner's motion for review of the Chief Special Master's decision on 15 June 2021. Order, ECF No. 126.

IV. Legal Standards

A. The Court's Standard of Review of a Special Master's Decision

The Vaccine Act provides this Court jurisdiction to review a Special Master's decision upon timely motion of either party. *See* 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing the record of the proceedings before the Special Master, the Court may: (1) "uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision;" (2) "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law;" or (3) "remand the petition to the special master for

further action in accordance with the court's direction." *Id.* § 300aa-12(e)(2). "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Saunders v. Sec'y of Dept. of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dept. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)).

It is not the Court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871). The Court also does "not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Id.* (quoting *Munn*, 970 F.2d at 871). "Reversal is appropriate only when the special master's decision is arbitrary, capricious, an abuse of discretion, or not in accordance with the law." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 718 (2009). The arbitrary and capricious standard "is a highly deferential standard of review:" "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dept. of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

B. The Standard of Causation in Vaccine Cases

"A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1341 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)). "A petitioner can show causation under the Vaccine Act in one of two ways": (1) "by showing that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table," in which case "causation is presumed"; or (2) "if the complained-of injury is not listed in the Vaccine Injury Table . . . the petitioner may seek compensation by proving causation in fact." *Id.* at 1341–42 (internal citations omitted). Vaccine cases employ a burden shifting standard: "[o]nce the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine." *Id.* at 1342 (citing *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); 42 U.S.C. § 300aa-13(a)(1)(B)).

"When a petitioner has suffered an off-Table injury . . . [the Federal Circuit] has established the following test for showing causation in fact under the Vaccine Act:"

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Broekelschen, 618 F.3d at 1345 (quoting *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Under the first prong of *Althen*, "[a] petitioner must provide a

'reputable medical or scientific explanation' for its theory." *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, [the explanation] must still be 'sound and reliable.'" *Id.* (quoting *Knudsen ex rel. Knudsen v. Sec'y of Dept. of Health & Human Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). Petitioners "need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act." *Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009). Where such evidence is introduced, it must not be viewed "through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. For satisfying the second *Althen* prong, "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280). Lastly, "the proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

V. Respondent's Disputes with the Chief Special Master's Decision

In its brief, respondent urges the Court to leave the Chief Special Master's decision undisturbed because the decision was not "arbitrary, capricious, an abuse of discretion, or not in accordance with law," and because the petitioner fails to show any "reversible error." Resp. to Mot. for Review at 1. Nevertheless, during oral argument, respondent revealed it does not fully agree with the Chief Special Master's decision. *See* Transcript, ECF No. 128 at 52:2–7 ("Tr.") (government counsel responding to the Court's observation that "it sounds like the [g]overnment does dispute certain aspects of the Chief Special Master's decision," by stating: "Yes. . . . I am not sure how this affects the outcome of the decision, but that is perhaps a different topic of discussion.")

Respondent disputes the Chief Special Master's conclusion that petitioner's injury is TM. *Id*. at 14:3–9 (Respondent's counsel stating, "[w]e disagree [with the Chief Special Master's conclusion that petitioner experienced TM]. We think that SCI was the proper finding, but that's not the decision he reached."). Respondent maintains it preserves the argument in its responsive brief, where it discusses the Chief Special Master's standard as applied to the "largely in equipoise" evidence in this case. *Id.* at 11:15–22, 12:5–9, 12:21–8. Respondent's counsel emphasized during oral argument, "If the topic for discussion [at oral argument] was the diagnosis of transverse myelitis, [r]espondent still believes that stroke was the proper diagnosis." *Id.* at 12:9–12.

On the Chief Special Master's conclusions surrounding *Althen* element one, respondent identifies a few aspects in the Baxter study where the Chief Special Master may have misconstrued the results due to lack of supporting information. Respondent recognizes the Chief Special Master's characterization of the Baxter study—"within a field of nearly 64 million vaccinations (including almost six million Tdap recipients) derived from data maintained by the

Vaccine Safety Datalink . . . [o]nly seven cases of TM were reported between 5-28 days post-vaccination"—is not a correct conclusion based on the data detailed in the study. Tr. at 79:9–4, 83:7–14 (respondent agreeing "that the [Chief] Special Master's language [on Baxter] . . . of seven cases of TM doesn't seem to be a correct conclusion based on the data that's detailed in the Baxter discussion."). According to respondent, "the supplementary data [of the Baxter study] . . . would perhaps be informative on this point," but the Chief Special Master did not "have the supplementary data and/or cite the supplementary data." *Id*. at 82:20–24, 83:15–17. Respondent also describes the Chief Special Master's statistical discussion of the Baxter study as "on his own provid[ing] more details about the statistical analysis that was conducted in Baxter [than] Dr. Zamvil testified about." *Id*. at 87:8–11.

Regarding *Althen* element two, respondent disagrees with the Chief Special Master's finding of I.J.'s symptom onset time. According to respondent, I.J.'s testimony during entitlement hearing does not support the Chief Special Master's finding that "prior to [I.J.'s first MRI scan on 8 August 2013], I.J. recalled being fully mobile," and "[i]mmediately following his MRI scan, however, I.J. lost all mobility from the neck down." *See* Tr. at 49:15–50:22; Decision at 8. Respondent contends I.J. referred to the timing of the CT scan as the point he started to lose mobility, not the MRI scan. Tr. at 42:22–43:8 (Respondent's counsel stated "[it] was the CT scan, not the MRI" "when I.J. was able to move his extremities [going in] and when he came out of the [scan] or immediately thereafter, he was not."). Respondent acknowledges the timing of I.J.'s loss of mobility is critical because such timing marked the onset of I.J.'s symptoms, but disputes whether the timing of the onset was the time the CT scan or the first MRI was taken. *Id*. at 42:2–4, 43:19–22 (Respondent's counsel stated "the goal here is to figure out when the MRI occurred.").

Respondent further disputes the Chief Special Master's *Althen* element 3 decision. The Chief Special Master decided "the record and evidence offered in this matter does support the conclusion that [p]etitioner's TM occurred in a medically acceptable timeframe, consistent with his causation theory." Decision at 43 (emphasis omitted). Respondent clarified at oral argument, "[r]espondent's position was that Petitioner did not meet *Althen* prong 3." Tr. at 7:7–8. Respondent is not contesting this issue simply because petitioner "did not raise this issue on appeal." *Id.* at 7:9–15. "[T]o the extent it wasn't raised on appeal," however, respondent expressed at oral argument it "does not provide any sort of objection." *Id*. at 7:10–12.

VI. The Chief Special Master's *Althen* Element One Decision

To prove causation in fact in an off-Table vaccine case, the petitioner must "show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The first element in *Althen* concerns whether a vaccine can cause petitioner's injury. *Id.* at 1279. Here, the Chief Special Master noted, "[a]s a threshold matter, . . . [p]etitioner has mischaracterized the evidentiary standard that is applied to the first *Althen* prong." Decision at 38. The Chief Special Master found petitioner erroneously "maintains that 'reliable scientific evidence' is not required to meet his preponderant

burden" and "suggests a theory's mere plausibility is enough to meet the preponderant standard—a contention that the Federal Circuit clearly rejected in the recent *Boatmon* decision." *Id.* (citing *Boatmon v. Sec'y of Health & Human Services*, 941 F.3d 1351, 1359 (Fed. Cir. 2019)). The Chief Special Master further found the Baxter study attached in Dr. Zamvil's report "greatly damages [p]etitioner's causation theory," because Baxter reported "[o]nly seven cases of TM . . . between 5-28 days post-vaccination" in "nearly 64 million vaccinations (including almost six million Tdap recipients)" and concluded "there was no reliably-demonstrated association between vaccination and the subsequent development of TM." *Id.* at 39 (emphasis omitted). Regarding petitioner's causation theory based on molecular mimicry, the Chief Special Master found, while molecular mimicry "is a generally accepted scientific explanation for many autoimmune diseases," petitioner's evidence failed to demonstrate molecular mimicry "likely does link the vaccine in question to the relevant injury." *Id.* at 41. The Chief Special Master recognized "prior decisions like *Raymo*, *Roberts*, and *Helman* [holding Tdap vaccine can cause TM injury] rely on literature similar to that offered [by petitioner in this case], or more broadly involve theories parallel with [p]etitioner's theory of autoimmunity attributable to molecular mimicry." *Id.* at 40 (internal citations omitted). Nevertheless, the Chief Special Master found these decisions are "diminished by more recent determinations involving the same causal theories producing TM." *Id.* (citing *Forrest v. Sec'y of Health & Human Servs.*, 14-1046V, 2019 WL 925495 at *3 (Fed. Cl. Spec. Mstr. Jan. 28, 2019)).

A. Petitioner's Burden of Proof in *Althen* Element One

To satisfy the first *Althen* factor, the petitioner must provide "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. The theory need not be corroborated by medical literature or epidemiological evidence. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). The Federal Circuit's instruction in *Andreu* is "[t]he first prong [of *Althen*] was satisfied . . . [when petitioner's expert] presented a 'biologically plausible' theory establishing that toxins in the whole-cell pertussis vaccine can cause seizures." *Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009); *see also Knudsen ex. rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 550 (Fed. Cir. 1994) (finding "it is entirely plausible, and contemplated by the statute, that DTP may cause an encephalopathy").

In his opinion, the Chief Special Master suggested the later Federal Circuit decision of *Boatmon* overruled *Andreu*'s biological plausibility standard for *Althen* element one. Decision at 38 ("Petitioner also erroneously suggests a theory's mere plausibility is enough to meet the preponderant standard—a contention that the Federal Circuit clearly rejected in the recent *Boatmon* decision."). In its 2019 *Boatmon* decision, the Federal Circuit stated: "we have consistently . . . reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon*, 941 F.3d at 1360 (citing *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010), *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (quoting *Moberly*, 592 F.3d at 1322)). It is noteworthy that the *Boatmon* court's holding specifies "a 'plausible' or 'possible' *causal* theory does not satisfy the standard." *Id.* (emphasis added). *Althen* articulates causation in fact in an off-table vaccine case has three elements: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278. In the section of the *Boatmon* opinion where the Federal Circuit rejected a merely "plausible" theory as sufficient to establish causation, the Federal Circuit was specifically analyzing the overall standard for "petitioners' burden to prove actual causation by a preponderance of the evidence in off-table cases," not a standard for *Althen* element one. *Boatmon*, 941 F.3d at 1360. The *Boatmon* court reserved a separate section to discuss *Althen* element one, where the court used "a sound and reliable medical theory of [causation]" as the legal standard to review the special master's decision. *See id.* at 1360–62.

A further reading into the *Moberly* and *LaLonde* decisions cited by the *Boatmon* court confirms the Federal Circuit did not overrule the "biological plausibility" standard for *Althen* element one. In *Moberly*, the Federal Circuit held petitioner erroneously characterized the standard for causation as "whether [petitioner's] condition was 'likely caused' by the DPT vaccine," and the Federal Circuit criticized the "likely caused" formulation being "something closer to proof of a 'plausible' or 'possible' causal link between the vaccine and the injury, which is not the statutory standard." *Moberly*, 592 F.3d at 1322. The *Moberly* court cited *Andreu* in discussing *Althen* element one, where the court distinguished *Moberly* from *Andreu* because "in *Andreu* . . . the government's expert witness did not dispute the biological plausibility of the theory . . . . In this case, by contrast, the government's expert witness did not concede the biological plausibility of the . . . theory, and in fact testified that people in the field don't think it's biologically plausible." *Id.* at 1325 (citing *Andreu*, 569 F.3d at 1377) (internal quotation marks omitted). Similarly, in *LaLonde*, the Federal Circuit held "a 'plausible' theory of causation is insufficient for a petitioner to meet [the] burden of proof" necessary for the petitioner to receive her requested relief in off-table vaccine case. *LaLonde*, 746 F.3d at 1339 (quoting *Moberly*, 592 F.3d at 1322). The Federal Circuit did not reject outright the "plausibility" standard for a *medical theory* in *LaLonde*, but instead said the petitioner must "show both the medical plausibility of her theory of causation and that the injury was consistent with that theory." *Id.* at 1340 (citing *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012)).

In *Kottenstette* v. *Sec'y of Health & Human Servs*, an unpublished Federal Circuit opinion issued on 15 June 2021 overruling the Court of Federal Claims for applying an incorrect legal standard, the Federal Circuit clarified the issue of the appropriate standard since *Boatmon*. *Kottenstette v. Sec'y of Health & Human Servs.*, No. 2020-2282, 2021 WL 2434329, at *1 (Fed. Cir. June 15, 2021). In *Kottenstette*, the special master summarized the *Althen* element one standard as "a search for 'medical probability rather than certainty'" and explained "'medical probability means biologic credibility rather than specification of an exact biologic mechanism.'" *Id.* at *6 (citing *Kottenstette v. Sec'y of Health & Human Servs.* (*Kottenstette I*), No. 15-1016V, 2020 WL 953484, at *2–3 (Fed. Cl. Feb. 12, 2020)). The Court of Federal Claims held the special master applied an incorrect legal standard, stating "biologic credibility is not sufficiently distinguishable from the 'plausible' or 'reasonable' standard that the Federal Circuit rejected in *Boatmon*." *Id*. (internal quotation marks omitted) (citing *Kottenstette I* at *3). The Federal Circuit in *Kottenstette* held "the . . . special master applied the correct legal standard. Thus, the . . . Court of Federal Claims decision vacating and remanding her decision is in error." *Id*. The court stated the special master's standard correctly follows the Federal Circuit's precedents "that

proof of causation does not 'require identification and proof of specific biological mechanisms.'" *Id.* at *7 (quoting *Knudsen,* 35 F.3d at 549). The Federal Circuit explicitly stated "*Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation." *Id*.

During oral argument, petitioner characterizes the *Althen* element one standard as: "a claimant's theory of causation must be supported by a reputable medical and scientific explanation." Tr. at 71:20–22. Respondent agrees with this standard and adds *Andreu* requires the explanation must be supported by "a simple preponderance of the evidence." *Id*. at 71:25–72:2, 71:4–7. Petitioner "absolutely" agrees the preponderant standard is applicable, but expresses the concern that "to apply [the preponderant standard] to the requirement of evidence for prong 1 . . . is not exactly correct," as "there's a conflict of concepts with [*Althen* element one and the evidential standard]," and "that may be where the confusion is." *Id*. at 67:25–68:3.

The Federal Circuit's *Kottenstette* decision came out after oral argument in this case, and therefore the Court did not have the opportunity to solicit the parties' opinions on the *Althen* element one standard in view of *Kottenstette*. Nevertheless, the Federal Circuit's clarification in *Kottenstette* resolves petitioner's confusion in applying the preponderant standard to *Althen* element one: "proof of causation does not 'require identification and proof of specific biological mechanisms,'" and "*Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation." *Kottenstette*, 2021 WL 2434329, at *7 (quoting *Knudsen*, 35 F.3d at 549). Accordingly, the Court finds the Chief Special Master erroneously suggested *Boatmon* overruled *Andreu*'s biological plausibility standard for *Althen* element one. *Andreu,* 569 F.3d at 1375 ("The first prong was satisfied . . . [when petitioner's expert] presented a 'biologically plausible' theory establishing that toxins in the whole-cell pertussis vaccine can cause seizures."); Decision at 38.

B. The Chief Special Master's Reliance on the Baxter Study as Providing "Comprehensive, Contrary Evidence"

Roger Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 CLIN. INFECT. DIS. 1456 (2016), referred by the Chief Special Master as the Baxter study, is Reference 12 in petitioner's expert Dr. Zamvil's report. ECF No. 32-3. Dr. Zamvil cited the Baxter study only once in his report, as a reference for his opinion that "[t]he association of transverse myelitis and Tetanus toxoid (TT)-containing vaccination was clear. As transverse myelitis following TDaP is a rare event, however, one should recognize that it has been challenging for epidemiologists to establish a relative risk." *See* ECF No. 31-1 at 7 (Dr. Zamvil's expert report); *see also* Decision at 13.

The Chief Special Master described Baxter as:

> "[A] large-scale, comprehensive epidemiological study aimed at examining the risk of demyelinating event following vaccination generally, and evaluated instances of the occurrence of two acute demyelinating diseases (TM and ADEM) within a field of nearly 64 million vaccinations (including almost six million Tdap recipients) derived from data maintained by the Vaccine Safety Datalink . . . [o]nly seven cases of TM were reported between 5-28 days post-vaccination—the very timeframe

> applicable herein. . . . Baxter concluded that there was no reliably-demonstrated association between vaccination and the subsequent development of TM."

Decision at 39 (emphasis and internal citations omitted). The Chief Special Master took special note that, while "Dr. Zamvil expressly relied on the Baxter article to support an association between TM and receipt of the Tdap vaccine," "his assertions regarding its findings essentially ignored what is so glaringly unfavorable about them." *Id.* at 39–40. The Chief Special Master acknowledged "Dr. Zamvil also relied on a series of case reports documenting instances of TM following vaccination," such as the Agmon-Levin reports, to support the association of TM and Tdap vaccines. Decision at 14. According to the Chief Special Master, Agmon-Levin reported four "TM [incidences] after receiving either the diphtheria-tetanus-pertussis vaccine or the diphtheria-tetanus vaccine" and "found seventy-three percent of TM cases were reported within one month of vaccination, consistent with the timeframe [I.J.] experienced." *Id.* The Chief Special Master found "[t]hese case reports overall had some evidentiary value . . . . But they are not enough to meet the preponderant burden, especially given the far more comprehensive, contrary evidence provided by Baxter." *Id.* at 42.

Petitioner strongly objects to the Chief Special Master's reliance on the Baxter study, maintaining "[t]he record is completely insufficient for the Chief Special Master to have placed the weight that he placed on Baxter . . . and that was the case breaker. . . . And there just was insufficient data, insufficient discussion, insufficient analysis for the Chief Special Master to draw the conclusions that he did." Tr. at 98:6–14. In particular, petitioner directs the Court to consider that "[t]he underlying data [in Baxter] was not filed," and "Dr. Zamvil's reliance on Baxter was for a very different purpose than what the Chief Special Master focused on." *Id.* at 98:17–19.

Respondent agrees with petitioner in many aspects. Respondent agrees "Dr. Zamvil used Baxter as a case summary report, and the [Chief] Special Master used Baxter as an epidemiological study." *Id.* at 101:24–102:2. Respondent further notes "the Chief Special Master on his own provided more details about the statistical analysis that was conducted in Baxter that Dr. Zamvil testified about." *Id.* at 87:8–11. Respondent notes the Chief Special Master's findings on the Baxter study are not supported by a close reading of the article and, while supplementary data is needed to understand the Baxter study, the Chief Special Master did not "have the supplementary data and/or cite the supplementary data." *Id.* at 82:19–83:17. In response to a question of why the Court should still uphold the Chief Special Master's decision with all these shortcomings, the respondent argues, "even if we were to ignore Baxter, the outcome would still be the same." *Id.* at 92:18–21.

1. The Data and Statistical Analysis in the Baxter Study

The Chief Special Master found "within a field of nearly 64 million vaccinations (including almost six million Tdap recipients) derived from data maintained by the Vaccine Safety Datalink . . . [o]nly seven cases of TM were reported between 5-28 days post-vaccination—the very timeframe applicable herein." Decision at 39. During oral argument, respondent helped the Court understand the correct reading of the Baxter study, based on the data reported in Table 1 and Table 4 of the article, should be "there was one total risk case per one

million doses of each vaccine," and respondent does not "see where that seven number comes from except in the results section [of the article's Abstract]." Tr. at 82:5–7, 82:19–22, 83:21–24 (When the Court asked respondent's counsel whether "the Court's assessment that Table 4 read together with Table 1 details that the total risk cases, the explanation is one TM case per 1 million vaccines administered," respondent's counsel replied "that's what Table 4 would suggest."). The Court therefore notes the Chief Special Master's reading of the Baxter study—seven cases of TM reported in 64 million vaccinations—does not accurately reflect the data in the article.

Respondent nevertheless suggested the Chief Special Master's mistaken reading of the numbers would not change the outcome, because the Baxter study noted "no increased risk was found for TM following Tdap and that . . . was a statistically significant conclusion." Tr. at 83:2–4; *see also* Decision at 39. On the Baxter study's statistical analysis, respondent agrees with the Court's suggestion that one important number in Table 4 of the study is the P value for each vaccine, because "[t]o reach a conclusion that a certain vaccine statistically increases the risk of TM, the P value would have to be lower than something similar to .05." Tr. 84:4–9. To calculate a P value for the purpose of rejecting or admitting an association, there must be a study group and a control group. [22] *See* Richard C. Dicker, *The CDC Field Epidemiology Manual*, EPIDEMIC INTELLIGENCE SERVICE, ANALYZING AND INTERPRETING DATA (Dec. 13, 2018), https://www.cdc.gov/eis/field-epi-manual/chapters/analyze-Interpret-Data.html#anchor_1543585004 (describing an alternative hypothesis will be adopted if the null hypothesis, the assumption being made, proves to be implausible). The Court struggles to understand from the Chief Special Master's decision what the control group is in the Baxter study, and respondent could not lend help except for speculating the information might be in the supplemental data which neither the Chief Special Master nor respondent had access to.[23] Tr. at 83:15–17, 85:3–7. Respondent further comments the Chief Special Master "on his own provided more details about the statistical analysis" than what was provided by Dr. Zamvil. *Id*. at 87:8–12. In conclusion, the Court finds both parties at least agree the Chief Special Master made important factual findings regarding the Baxter study without being presented with sufficient evidence to support the findings.

Respondent suggests the Court focuses on Dr. Zamvil's testimony regarding the Baxter study, where Dr. Zamvil testified "the case control study was a fairly reliable type of evidence" that revealed no statistically significant increased risk of immunization for TM. *Id*. at 90:1–6.

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[22] Basic statistics books, including Gary L. Tietjen, A Topical Dictionary of Statistics at 37–38, and the CDC website, Richard C. Dicker, *The CDC Field Epidemiology Manual*, EPIDEMIC INTELLIGENCE SERVICE, ANALYZING AND INTERPRETING DATA (Dec. 13, 2018), https://www.cdc.gov/eis/field-epi-manual/chapters/analyze-Interpret-Data.html#anchor_1543585004, can help understand the Chief Special Master's statistical findings in reference to the Baxter Study. A p-value is the probability of finding an association as strong as, or stronger than, the one observed if the null hypothesis were true. A small p-value means the null hypothesis is implausible. If p-value is smaller that a predetermined cutoff, the null hypothesis is rejected in favor of the alternative hypothesis. A rejection of the null hypothesis means the association is statistically significant.

[23] On page 21 of the Chief Special Master's decision, he wrote "Dr. Levin compared incidence rates between TM and spinal cord infarction, finding that . . . TM is . . . occurring in 3 per 100,000 person-years." This is the only possible, though seemingly remote, information about the Baxter study's control group the Court could identify throughout the Chief Special Master's decision. Tr. at 85:8–14. Respondent's counsel explained to the Court the question is beyond her level of statistical knowledge, and Dr. Levin, who supplied the "TM occurring in 3 per 100,000 person-years" statement, did not testify about the Baxter study. *Id*. at 86:7–22.

The Court notes, and respondent agrees, Dr. Zamvil relied on the Baxter study for a different purpose than the Chief Special Master did. *Id*. at 90:7–9; *see also id*. at 101:24–102:2 (Respondent's counsel agreeing "Dr. Zamvil used Baxter as a case summary report, and the Special Master used Baxter as an epidemiological study."). Respondent suggests "for what the Chief Special Master understood the holdings of Baxter to be," he assigned correct weight to the Baxter study in his decision, but at oral argument before the Court "shed some additional light on what Baxter stands for more." *Id*. at 106:8–16. Respondent specially notes the discussion of lack of supplementary data and what Table 4 of the Baxter study shows. *Id*. at 101:18–20. Given the "additional light" oral argument shed on the Baxter study, respondent maintains "the Baxter study has some value in terms of its conclusions regarding no association between TM and [Tdap vaccine]." *Id*. at 101:21–23.

Respondent agrees it is a "fair statement" that "a large-scale statistical study . . . has a whole lot of data in it that stands for a variety of things" and "that the statistical value that Dr. Zamvil, as an expert who probably also had access to all of the underlying data used in one calculation, is far different than the statistical analysis used to describe a conclusion related [to] something else, especially without a statistical background and review of the underlying data and regressions and calculations." Tr. at 90:16–91:2. In this case, the record is too incomplete for the Chief Special Master to draw plausible inferences from the simple statistical conclusion presented by the Baxter study. Furthermore, the Chief Special Master relied on the Baxter study as "far more comprehensive, contrary evidence" to counter the probative value of other evidence by the petitioner, such as the Agmon-Levin case reports, and "the far more comprehensive contrary evidence provided by Baxter" is connected with the numbers the Chief Special Master discussed as related to Baxter. Decision at 42; *see also* Tr. at 88:2–13. As discussed above, the Chief Special Master's findings of the numbers in Baxter, including a plain reading of the data and the statistical analysis, is not supported by the record.

Accordingly, the Court finds the Chief Special Master's decision that the Baxter study provides "far more comprehensive, contrary evidence" is not supported by the record, and thus is arbitrary and capricious. *Saunders v. Sec'y of Dept. of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dept. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)) ("Fact findings are reviewed . . . under the arbitrary and capricious standard."); *see also Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1380 (Fed. Cir. 2015) ("Where, as here, a special master . . . misconstrues [a petitioner's] medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law.").

2. The Chief Special Master's Consideration of the Baxter Study in Other Cases

The 2016 Baxter study collected and analyzed data for 18 types of vaccines from the CDC's Vaccine Safety Datalink, and concluded "[f]or TM, we found no evidence of a safety concern, or any association with subsequent illness [for any of the 18 vaccines]. If there is any association, it is <1 per million doses for vaccines other than live zoster and live attenuated influenza vaccines, and <2 per million doses of these 2 vaccines." Baxter study at 1461. For

some vaccines including Hepatitis B, the Baxter study concluded there is zero risk case per one million vaccine receivers. *Id.* at 1460. The Chief Special Master considered the Baxter study in other cases since the study's publication, including *Bender v. Sec'y of Health & Human Servs.*, 11-693V, 2018 WL 3679637 (Fed. Cl. Spec. Mstr. Jul. 2, 2018) and *McGrail v. Sec'y of Health & Human Servs.*, 17-926V, 2021 WL 1728706 (Fed. Cl. Spec. Mstr. Apr. 23, 2021).

In *Bender*, the Chief Special Master denied compensation for TM the petitioner alleged was caused by the Hepatitis A and meningococcal vaccines. *Bender*, 2018 WL 3679637 at *1–2. The respondent in Bender offered the Baxter study to undermine petitioner's causation theory for TM. *Id.* at *30. The Chief Special Master considered the Baxter study but concluded it did not "stand as [his] primary basis for finding the [p]etitioner did not establish a plausible causation theory." *Id.* Petitioner's *Althen* element one demonstration in *Bender* failed for many reasons, including petitioner providing no evidence linking the particular vaccines to her injury and her experts "being significantly less persuasive" than respondent's. *Id.* at *29, 31.

In *McGrail*, the Chief Special Master awarded compensation for TM the petitioner was able to show—by a preponderance of evidence—was caused by the Hepatitis B vaccine. *McGrail*, 2021 WL 1728706 at *1. As with *Bender*, the respondent offered Baxter to undercut petitioner's causation theory. *Id.* at *26. The Chief Special Master considered Baxter and found it "does undercut [p]etitioner's showing." *Id.* The Chief Special Master nevertheless found the petitioners successfully met the *Althen* element one burden for the following reasons: petitioners' experts "offered enough reliable scientific and medical evidence [including molecular mimicry and case studies] . . . to provide a preponderant 'can cause' theory relating the Hepatitis B vaccine to TM"; "existing [Vaccine] Program decisions [finding causation between Hepatitis B and TM] also helped [p]etitioners"; and treaters' opinions pointing out Hepatitis B as the likely cause of the disease. *Id.* at 25. The Chief Special Master concluded petitioners "barely met their preponderant burden on this first element," and "well-reasoned and controlling precedent in the Vaccine Program requires" the Chief Special Master "in such close cases to decide the matter for the petitioner." *Id.* at 26.

Petitioner argues the Chief Special Master's reliance on the Baxter study in this case is "undue and burden-heightening" compared to his discussion of Baxter in *Bender*. Mot. for Review at 32. Petitioner was not aware of *McGrail* at oral argument, but respondent brought it to the Court's attention to demonstrate the Baxter study does not block every vaccine compensation claim. Tr. at 96:24–97:13, 102:3–7. Respondent argues *McGrail* is distinguishable from the present case because the respondent, rather than the petitioners, was the party in *McGrail* which offered Baxter to support its position, but respondent could not offer a legal explanation to justify different interpretations of evidence when offered by different parties. *Id*. at 104:5–105:9. Respondent does not dispute the Chief Special Master read Baxter in a more favorable light for petitioner in *McGrail*, regardless of Baxter finding zero increased risk for Hepatitis B per one million doses. *Id*. at 105:9–20 (respondent stating "all [she] can say [on Baxter being read in a more favorable light in *McGrail*] is that each case is very specific to the facts and the evidence and findings of the Chief Special Master, and one decision is not binding on another."). Respondent nevertheless maintains, "to the extent that the Chief Special Master reached a different decision about Baxter in a different case with different evidence and a different vaccine, . . . that's something that he is allowed to do as a Chief Special Master." *Id*. at

106:1–6. Respondent further noted, in *McGrail*, the Chief Special Master credited a previous omnibus proceeding which found Hepatitis B was causal of TM. *Id*. at 106:21–24. In the present case, the Chief Special Master acknowledged several previous decisions finding Tdap being causal of TM, but refused to credit these decisions. Decision at 40 (citing *Roberts v. Sec'y of Health and Human Servs.*, No. 09-427V, 2013 WL 5314698 (Fed. Cl. Spec. Mstr. Aug. 29, 2013); *Raymo v. Sec'y of Health & Human Servs.*, No. 11-0654V, 2014 WL 1092274 (Fed. Cl. Spec. Mstr. Feb. 24, 2014); *Helman v. Sec'y of Health and Human Servs.*, No. 10-813V, 2012 WL 1607142 (Fed. Cl. Spec. Mstr. Apr. 5, 2012)). Respondent explained the Chief Special Master's contrasting treatment of previous decisions in *McGrail*, as compared to this case, is due to the factual and procedural differences linking vaccines to TM. Tr. at 107:17–108:23.

The Chief Special Master assigned consistent weight to the Baxter study in *Bender* and *McGrail*: The Chief Special Master found the Baxter study "does undercut [p]etitioner's showing," but he either decided it was not sufficient to rebut petitioner's *Althen* element one showing or it did not "stand as [the] primary basis for finding the [p]etitioner did not establish a plausible causation theory." *McGrail*, 2021 WL 1728706 at *26; *Bender*, 2018 WL 3679637 at *30. In this case, the Chief Special Master found the Baxter study provided "far more comprehensive, contrary evidence" against petitioner's *Althen* element one showings. Decision at 42. Petitioner complains the Chief Special Master elevated the Baxter study to "not the tie-breaker, but the case-breaker" weight in this case despite the record being "completely insufficient for the Chief Special Master to have placed the weight that he placed." Tr. at 98:5–11. Respondent describes the Baxter study in *McGrail* as "just one element," and "in and of itself, . . . not a tie-breaker." *Id*. at 97:9–10.

Regarding the Baxter study itself, the only difference in the weight of the study between this case and in *Bender* and *McGrail* is the fact Baxter was offered as petitioner's evidence in this case, and I.J. offered the Baxter study to show possible association between Tdap vaccine and TM. The Chief Special Master read the Baxter study differently than petitioner's expert, finding the expert "essentially ignored what is so glaringly unfavorable" to petitioner in Baxter. Decision at 40. The Court understands special masters are not required to distinguish other relevant cases. *Boatmon*, 941 F.3d at 1358. The Chief Special Master cannot, however, read the exact same evidence differently in different cases solely because it is offered by a different party. Here, the Court finds the Chief Special Master's conclusion that the Baxter study provided "far more comprehensive, contrary evidence" in this case troublesome because of the stark contrast in the weight the Special Master's assigned to the Baxter study in this case versus *Bender* and *McGrail*.[24]

[24] The Baxter study does not completely disavow the association of TM and vaccines, but rather claimed "[i]f there is any association, it is <1 per million doses for vaccines other than live zoster and live attenuated influenza vaccines, and <2 per million doses of these 2 vaccines." Baxter study at 1461. An extremely low rate of association does not preclude the possibility of compensation, especially in view of the statutory purpose of the Vaccine Act. *See Boatmon*, 941 F.3d at 1364 (Newman, P., dissenting) (quoting *National Childhood Vaccine-Injury Compensation Act*: *Hearing on S.2117 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 3–4 (1984) ("These few but important injuries create doubts and fears in our National Childhood Vaccination Programs. . . . We must be able to assure parents that when their children are the victims of an appropriate and rational national policy, a compassionate Government will assist them in their hour of need.")). Respondent maintains vaccine compensation is not predicated upon any particular rate of association between the injury and the vaccine. Tr. at 95:22–96:3 (When asked if "the rate of one in a million [is] too low for vaccine compensation," respondent's counsel stated "I

C. The Chief Special Master's Finding Related to Petitioner's Burden of Proof for Molecular Mimicry Theory

Petitioner relied on molecular mimicry to show the Tdap vaccine can cause TM. Mot. to Review at 32. Petitioner's expert found homologies between a protein antigen in Tdap and human myelin proteins as "supporting the principle that TDaP has potential to activate the immune response to CNS autoantigens." *Id.* The Chief Special Master acknowledged molecular mimicry is a "generally accepted scientific explanation for many autoimmune diseases." Decision at 41. The Chief Special Master also acknowledges previous cases, including *Raymo*, *Roberts*, and *Helman*, found Tdap vaccines can cause TM, but concluded "the applicability of prior decisions like *Raymo*, *Roberts*, and *Helman*—all of which rely on literature similar to that offered herein, or more broadly involve theories parallel with [p]etitioner's theory of autoimmunity attributable to molecular mimicry—is . . . diminished by more recent determinations involving the same causal theories producing TM." Decision at 40 (citing *Forrest*, 2019 WL 925495, at *3).

Petitioner argues *Forrest* was wrongly decided because it "runs afoul of the principle that petitioners in the Vaccine Program need not prove their cases with scientific certainty." Mot. to Review at 34 (citing *Moberly*, 592 F.3d at 1322). Respondent agrees "*Forrest* is not consistent with *Raymo*, *Roberts*, and *Helman*." Tr. at 116:14–21. Respondent further argues *Forrest* is significantly distinguishable from *Raymo*, *Roberts*, and *Helman* because *Forrest* addressed a petitioner seeking compensation under the claim the flu vaccine caused their TM. *Id*. at 117:7–17. Respondent also argues *Raymo*, *Roberts*, and *Helman* were wrongly decided, because "if the *Forrest* standard was held to those cases, those petitioners would not have established molecular mimicry." *Id*. at 115:23–116:21 ("I don't think that *Raymo* and *Roberts* were correctly decided or that the appropriate standard was used there. . . . I agree the *Forrest* decision is not consistent with *Roberts*, *Raymo*, . . . [and] *Helman*."). Respondent explains "in *Roberts*, the Special Master discusses how molecular mimicry is plausible," but "*Boatmon* made very clear that plausib[ility] is insufficient." *Id*. at 116:4–10.

As discussed in Section VI(A), the Federal Circuit warned "*Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation." *Kottenstette*, 2021 WL 2434329, at *7. The "biological plausibility" standard still applies for *Althen* element one. *Andreu*, 569 F.3d at 1375 ("The first prong was satisfied . . . [when petitioner's expert] presented a 'biologically plausible' theory establishing that toxins in the whole-cell pertussis vaccine can cause seizures."). Accordingly, to the extent the Chief Special Master found *Forrest* discredited *Raymo*, *Roberts*, and *Helman* because *Boatmon* abolished the plausibility standard of *Andreu*, the Chief Special Master's decision is "not in accordance with law." *Saunders*, 25 F.3d at 1033

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don't think that vaccine compensation is predicated upon any particular rate."). As respondent notes, a zero rate of association between Hepatitis B and TM reported by Baxter did not preclude the Chief Special Master from awarding award compensation in *McGrail*. *Id*. at 96:24–97:13; Baxter study at 1460. Respondent further notes "the Baxter study— like all epidemiological studies—can never prove definitively that Factor A never causes Condition B." Resp. to Mot. for Review at 12 (internal quotation marks omitted) (citing *Bender*, 2018 WL 3679637, at *30 (quoting *Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-0039V, 2014 WL 1665227, at *15 (Fed. Cl. Spec. Mstr. Apr. 7, 2014))); *see also* Tr. 100:10–16 ("[N]o study can say that a vaccine can't cause a particular injury . . . . That's just an impossible thing for any epidemiological study to establish.").

(quoting *Munn*, 970 F.2d 870 n.10) ("[L]egal questions [are reviewed] under the 'not in accordance with law' standard."); Decision at 40 (citing *Forrest* in support of the prospect "the applicability of prior decisions . . . [is] diminished by more recent determinations involving the same causal theories producing TM."). On remand, the Chief Special Master should review petitioner's molecular mimicry showings under the correct legal standard.[25]

D. Conclusion Regarding *Althen* Element One

The Court does not address the question of whether petitioner offered sufficient evidence to establish *Althen* element I through the molecular mimicry standard. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871) (noting it is not the reviewing court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence.").[26] Rather, the Court finds the Chief Special Master applied an incorrect legal standard to weigh the evidence and that such a decision was arbitrary, capricious, and not in accordance with law. *See supra.* On remand, the Chief Special Master should reweigh the parties' arguments under the correct legal standard.

VII. The Chief Special Master's *Althen* Element Two Decision

The second *Althen* element concerns whether the vaccine *did* cause petitioner's injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Chief Special Master discussed *Althen* element two and element three after he decided petitioner failed to prove *Althen* element one. Decision at 42 ("Petitioner's claim cannot succeed, given his failure to meet at least one of the three *Althen* prongs. . . . However, for purposes of completion of my overall analysis, I will also discuss his success in meeting the other two."). The Chief Special Master found petitioner failed to meet *Althen* element two due primarily to two evidentiary shortcomings: (1) "there was hardly any testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation—a telltale sign confirming the presence of the autoimmune process that [p]etitioner's causation theory proposes"; and (2) "no treaters ever proposed that [p]etitioner's injury, however defined, was likely caused by his prior Tdap vaccine." *Id.* at 41–42.

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[25] The *Forrest* decision was not reviewed by this court or the Federal Circuit. Therefore, the *Forrest* standard has no precedential value.

[26] Petitioner relied on BLAST search results to find homologies between a protein antigen in Tdap to human myeline proteins, which supports petitioner's molecular mimicry theory. Mot. to Review at 26. Respondent criticizes the use of BLAST as "a case-oriented search and therefore . . . less reliable and persuasive." Tr. at 112:13–16. Respondent further maintains Dr. Zamvil "kind of stopped with the homology," and argues "those sequences alone are [not] enough to establish that they would be biologically meaningful and would actually result in autoantibodies." *Id.* at 114:2–10; see also Decision at 41 ("[M]erely demonstrating some homology between vaccine components and relevant self-structures based on computer database searches does not carry the day."). Petitioner directs the Court to look at Dr. Zamvil's report beyond only the BLAST search, noting "he went on to explain in detail the mechanisms supported by the medical literature, how it could cause this injury." Tr. at 118:14–20. Petitioner characterizes the BLAST search as "just one confirmatory tool based on a government database that was used to support the theory, conforming with the requirement that there be an explanation that's reliable and reputable." *Id.* at 118:22–1. Whether Dr. Zamvil's approach is sufficiently reliable and persuasive to meet the preponderance of evidence standard is a question best addressed by the Chief Special Master on remand. *Lampe*, 219 F.3d at 1360.

A. Testing Evidence of Inflammation

The medical definition of transverse myelitis is inflammation of the spinal cord in which the functional effect of the lesions spans the width of the entire cord at a given level. *W.A. Newman Dorland*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1201 (33rd ed. 2020). Respondent's expert, Dr. Alexander, provided the same definition of TM to the Chief Special Master: "Transverse myelitis . . . is defined by finding evidence of inflammation, seen either by gadolinium enhancement on MRI or CSF pleocytosis, or both." Alexander Ex. Rep. 1 at 9; *see also* Decision at 22 (citing 2019 Tr. at 301:10–11 (Dr. Alexander testifying, "[t]ransverse myelitis describes, you know, an inflammation of the cord.")). According to the TM Working Group criteria, the application of which both parties agreed with before the Chief Special Master, inflammation is one inclusion criteria for diagnosing TM. Decision at 35 ("The parties seemed to agree that the TM Working Group criteria were a good general yardstick for evaluating if TM was present in this case."); Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis, ECF No. 63-4 at 500 (Diagnosis criteria established by the Transverse Myelitis Consortium Working Group). During oral argument, respondent again confirms, "[t]o the extent that Dr. Alexander testified that transverse myelitis is inflammation of the spinal cord, in many cases that's correct. . . . [M]yelitis literally means inflammation of the spinal cord." Tr. at 21:16–19.

Petitioner argues the Chief Special Master's conclusion petitioner suffered from TM internally contradicts the finding of no inflammation. Mot. for Review at 37 ("The [Chief] Special Master relied upon a purported absence of inflammation as undermining the diagnosis of TM. The [Chief] Special Master himself also suggested the possibility that the TM . . . might have been prompted by a respiratory infection."). At oral argument, respondent tried to defend the Chief Special Master's decision by arguing it is the petitioner's burden, not respondent's, "to prove whether or not there's inflammation." Tr. at 25:23–25. At oral argument, respondent told the Court inflammation is "an essential piece . . . to have transverse myelitis, and especially vaccine-induced transverse myelitis," and the Chief Special Master's decision "was not faithful to the transverse myelitis working group." *Id*. at 23:3–5, 23:24–24:2. Respondent further stated it is "essentially correct" to summarize the government's position as: "there was no inflammation of the [p]etitioner's spinal cord[,] and that a lack of inflammation of the spinal cord should have resulted in the [Chief] Special Master concluding that there was not TM[,] and that the conclusion that there was TM was inconsistent with the finding of no inflammation of the spinal cord." *Id*. at 24:11–18. The discussion with respondent on the relationship of inflammation and TM reveals both petitioner and respondent hold the position that the Chief Special Master's decision on TM is inconsistent with his finding of no inflammation.

Petitioner maintains the Chief Special Master's statement that "there was hardly any testing [to support inflammation]" and his "dismissal of the testing" is arbitrary and capricious. *Id*. at 35:20–21; *see also* Mot. for Review at 37 ("The [Chief] Special Master's interpretation of the medical record was arbitrary and capricious, requiring reversal. Moreover, the Decision by the Special Master was rendered irrational by an internal inconsistency fundamental to [p]etitioner's case") (emphasis omitted). The government agrees "[I.J.] underwent a number of tests. It's [respondent's argument] that those tests didn't show inflammation." Tr. at 36:20–21.

Petitioner first cites to the MRI testing done on 17 August 2013 ("17 August MRI") as supporting inflammation. Mot. for Review at 37–38. I.J.'s medical record shows he underwent two rounds of MRI testing, one on 8 August 2013 ("8 August MRI"), and the other on 17 August 2013. Med. Recs. 50-2 at 1–2; Med. Recs. 8-2 at 10; *see also* Tr. at 28:6–8, 29:2–4 (Petitioner's counsel stating, "I don't think there were more than two MRIs," and respondent's counsel stating, "I agree with [petitioner's counsel], there was only one second MRI conducted."). The parties do not dispute the 8 August MRI did not show inflammation, and petitioner explained this is because "TM typically shows a lack of inflammation early in the disease process." Mot. for Review at 37; *see also* Tr. at 37:22–24 ("Respondent's expert opined that only the second MRI, the 8/17 showed any sort of enhancement."); Mot. for Review at 37 ("[W]hile there was no gadolinium enhancement on the initial MRI, the follow up just a few days later did so reflect gadolinium enhancement."). The parties do not dispute the 17 August MRI showed enhancement that was not in the 8 August MRI, but disagree on whether the enhancement is inflammation. Tr. at 29:19–22 (Petitioner arguing "that the August 17th MRI . . . show[s] inflammation."), 37:24–38:2 (Respondent's counsel arguing "8/17 is like nine days post onset. That's much too late to show evidence of inflammation if we are going to decide that this is transverse myelitis."). Respondent argues, because the 17 August MRI was taken outside the 2–7 day post-onset window, "it's difficult to relate that back . . . to a vaccine or an immune-mediated event." *Id*. at 41:14–21. Nevertheless, respondent could not identify the exact onset time of I.J.'s symptoms—whether at the CT scan or the first MRI—and disputes the Chief Special Master's finding. *See supra* Section V.[27] Petitioner argues, whether or not the 8 August MRI marked the onset of I.J.'s symptoms, "[the 17 August MRI] was not so widely outside [the 2–7 day post onset window] that it's not relevant. It's highly relevant and reflected the change in I.J.'s condition and reflected the change in the presences of inflammation, which was a key point on this logical sequence of cause and effect." Tr. at 54:4–9.

When presented with the 17 August MRI imaging during oral argument, petitioner's counsel was not able to explain to the Court how the enhanced signals are indicative of inflammation and stated he would defer this issue to the expert report of Dr. Watanabe, who "was credited in the hearing." *Id*. at 30:24–31:25. Respondent's counsel did not offer to explain how the imaging does not support an interpretation of inflammation, but at a later stage of the oral argument counsel returned to the point to argue the enhanced signals "supported a spinal cord infarct" based on the findings on diffusion-weighted imaging of the 17 August MRI. *Id*. at

[27] During oral argument, respondent's counsel for the first time questioned the Chief Special Master's finding of I.J.'s symptom onset time. *See* Tr. at 51:1–10 (Respondent agreeing "[t]he [g]overnment disputes the [Chief] Special Master's conclusion that prior to his scan, I.J. testified to being . . . fully mobile."); Decision at 8 ("Prior to his scan, [I.J.] recalled being fully mobile. Immediately following his MRI scan, however, [I.J.] lost all mobility from the neck down.") (internal citations omitted). Respondent contends I.J. referred to the timing of the CT scan when he started to lose mobility, not the MRI scan. Tr. at 42:22–43:8 (Respondent's counsel stated "that was the CT scan, not the MRI" "when I.J. was able to move his extremities and when he came out of the [scan] or immediately thereafter, he was not."). Respondent acknowledges the timing of I.J. losing mobility is critical because such timing marked I.J.'s symptom onset, *id*. at 42:2–4, but respondent disputes the timing of the onset. *Id*. at 43:15–22 (Respondent's counsel stating, "the goal here is to figure out when the MRI occurred. And so I don't want to hold up the discussion by having a dispute about whether it was the CT scan or the MRI.").

63:1–15.[28] I.J.'s medical record shows his treating physicians considered the differential diagnosis between TM and SCI after the 17 August 2013 MRI and ordered CT angiogram for "further evaluation of spinal arterial supply." Med. Recs. 8-3 at 230–231; *see also* Decision at 4 ("Based on these results [of the 17 August MRI], I.J.'s differential diagnosis was narrowed to encompass only TM and spinal cord infarction—though the diagnosis of TM was identified as favored due to 'the age of [I.J.], the repeat occurrence, and the holocord involvement, and the cervical location' of the lesion."). Regarding the results of the CT angiogram, petitioner explains "there was no cutoff of the artery . . . be[ing] seen in [the CT] angiogram . . . which is inconsistent with there being an infarct." Tr. at 33:2–5. Respondent does not dispute the CT angiogram did not show an embolus or thrombus, but respondent's expert states "[o]ne would not expect to find embolus or thrombus thirteen days after an infarct." Alexander Ex. Rep. 2 at 2.

Respondent does not offer specific evidence to directly negate the interpretation of the 17 August MRI as indicating inflammation. Respondent's argument regarding the 17 August MRI rather primarily concerns on it being taken outside the 2–7 day post onset window and the enhancement possibly being indicative of an infarction. Tr. at 41:14–21, 63:1–15. Nevertheless, the government disputes the onset time and could not reconcile the different outcomes of the 17 August MRI and the CT angiogram, despite these two tests being taken in a close timeframe. *See supra*. The Chief Special Master acknowledges the 17 August MRI narrowed I.J.'s differential diagnosis "to encompass only TM and spinal cord infarction—though the diagnosis of TM was identified as favored." Decision at 4.

Regarding the serologic sampling test, respondent suggested "testing of the cerebrospinal fluid . . . show[ing] an elevated white blood cell count" can point to inflammation and noted I.J.'s medical record does not contain such evidence. Tr. at 41:7–11. I.J. underwent a CSF test around the same time as the first 8 August MRI test. *See* Mot. for Review at 22 n. 17. Petitioner does not dispute "the CSF came back negative for pleocytosis (elevated white blood cell count)." *Id*. at 38. Petitioner explains however, consistent with the 8 August MRI showing no inflammation, "this is common and is seen to occur in 43% of patients diagnosed with TM." *Id.* There was no repeat CSF test done after the 17 August MRI. Tr. at 55:9–12. Respondent agrees, "for the purpose of finding inflammation," it is significant that there was no repeat CSF test done when "[t]he first MRI . . . shows something different than the second MRI." Tr at 55:19–24. Respondent argues the fact no CSF test was repeated supports the finding of no inflammation, because "if [the physicians] had suspected ongoing inflammation [they] would have conducted another CSF exam." Tr. at 56:7–9. Respondent's argument regarding the CSF test, as best, finds no support in the medical record, if not being completely speculative. The fact that a CSF test was not properly repeated after the 17 August MRI test possibly captured inflammation should not be construed as evidence against the finding of inflammation. Accordingly, the Courts finds the record does not support the Chief Special Master's finding that "there was hardly *any* testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation." Decision at 42 (emphasis added).

[28] Respondent emphasized during oral argument Dr. Alexander filed a supplemental expert report explaining how apparent diffusion coefficient and diffusion-weighted imaging supports reading the enhanced signals in the 17 August MRI as spinal cord infarction. Tr. at 63:3–11.

Petitioner further argues I.J.'s positive response to treatment addressing inflammation is indicative of him having inflammation. Mot. to Review at 38 ("The TM diagnosis, and an attempt by the treating physicians to address inflammation, was further supported by the course of treatment provided . . . and the fact that he responded positively to these efforts, showing 'some improvement' strongly suggesting the presence of inflammation."). Respondent agreed "the positive response [I.J.] experienced from that treatment evidence *can* support inflammation," but insisted "[r]espondent's expert did not feel that [p]etitioner's improvement was as drastic as [p]etitioner testified." Tr. at 56:24–57:5 (emphasis added). The Chief Special Master acknowledged I.J.'s positive response to anti-inflammatory treatment in numerous places throughout the decision, but he did not consider the positive response as evidence supporting existence of inflammation. Decision at 3 ("From August 9 to 15, 2013 [I.J.] was treated with Solumedrol, intravenous immunoglobulin ("IVIG"), and plasma exchange ("PLEX")."); *id.* at 13 n.16 ("Solumedrol is an anti-inflammatory synthetic glucocorticoid." "IVIG therapy is used to treat immune system disorders.") (citations omitted); *id.* at 4 (Dr. Eddie Louie "observed that [p]etitioner's symptoms were improving with steroid and IVIG treatment."); *id.* at 5 (Dr. Stephanie Sterling "acknowledged that [p]etitioner's condition was improving with steroids, IVIG, and PLEX treatments."); *id.* at 8 (I.J. testified "[f]ollowing treatment with IVIG and plasmapheresis, [I.J.] regained some mobility in his arms.").

In view of the inherent inconsistency of a TM diagnosis and absence of inflammation, the result of I.J.'s 17 August MRI test, and I.J.'s positive response to anti-inflammatory treatment, the Court finds the Chief Special Master's factual finding—"there was hardly *any* testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation"—is arbitrary and capricious. *Saunders v. Sec'y of Dept. of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting *Munn v. Sec'y of Dept. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)) ("Fact findings are reviewed . . . under the arbitrary and capricious standard."); *see also Paluck v. Sec'y of Health & Human Servs.,* 786 F.3d 1373, 1380 (2015) ("Where, as here, a special master . . . misconstrues his medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law."); *Andreu v. Sec'y of Dept. of Health & Human Servs.,* 569 F.3d 1367, 1375 (2009) (concluding that a special master erred in disregarding probative testimony from a petitioner's treating physicians); *Mondello v. Sec'y of Dept. of Health & Human Servs.,* 132 Fed.Cl. 316, 323–25 (2017) (finding the special master "erred in her conclusion that petitioner's claim had to be dismissed for not providing any evidence of a theory of causation" when "there are [doctor's notes and records] and other pieces of evidence submitted by petitioner that arguably lend some support to his claim"). The Court does not address whether the evidence petitioner presented ought to have changed the Chief Special Master's decision, nor does the Court consider whether the evidence is sufficient to establish *Althen* element two. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting *Munn*, 970 F.2d at 871) (finding it is not the reviewing court's role "to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence."). That is left to the Chief Special Master on remand.

B. Treater's Opinions

In deciding petitioner failed to meet *Althen* element two, the Chief Special Master found "no treaters ever proposed that [p]etitioner's injury, however defined, was likely caused by his prior Tdap vaccine." Decision at 43. The Chief Special Master identified two occasions in the medical records where I.J.'s treating physicians mentioned a possible association between his injury and his vaccine record: "Dr. Eddie Louie, M.D., who (mistakenly believing [I.J.] had received the Hepatitis B rather than Tdap vaccine) noted that a causal connection between the Hepatitis B vaccine and TM has been identified," and Dr. Jessica Taff, who "also expressed a desire to obtain [I.J.'s] immunization history due to reports of TM following receipt of the Hepatitis B vaccine." *Id.* at 4, 6. The Chief Special Master considered the treaters' opinions, and he drew the inference that "[a]t most, the record reveals instances in which treaters assumed [p]etitioner had received a different vaccine (Hepatitis B) that they believed could be associated with TM." *Id.* at 43.

Petitioner emphasized at oral argument the fact "that the treaters did consider vaccines." Tr. at 61:20–21. Petitioner acknowledges "there was some error" in the treaters' beliefs, but since the treaters were "just trying to figure out what happened," "to say . . . no treaters ever proposed [p]etitioner's injury . . . was likely caused by his prior Tdap vaccine is not exactly accurate." *Id*. at 61:21–62:3. Petitioner contends "to focus on [the treaters' errors] in the . . . element [two] analysis is not appropriate." *Id*. at 62:7–9. Respondent agrees "the Chief Special Master does note that treating physicians did discuss vaccines." *Id*. at 59:24–60:1. Respondent contends, however, "to the extent [treaters' opinion over a vaccine-related injury] was confounding with [treaters' mistakenly tracking the type of vaccine that was received], . . . it's not particularly persuasive evidence." *Id*. at 60:17–19. Respondent further informs the Court "if a medical provider provides a causation opinion about a particular vaccine causing an injury, that's particularly . . . deserving of great weight." *Id*. at 60:20–23. "But here, if we have a statement about vaccines generally, . . . it's less informed than a statement about a particular vaccine causing a particular reaction." *Id*. at 60:23–61:1.

Opinions of treating physicians are "quite probative," because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280). Treaters' opinions in the medical records "warrant consideration as trustworthy evidence," because these records are "generally contemporaneous to the medical events," and the "accuracy has an extra premium." *Cucuras v. Sec'y of Dept. of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *see also Andreu*, 569 F.3d at 1375 ("[T]reating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.") (citations and internal quotation marks omitted). Here, the Chief Special Master considered the opinions of Drs. Louie and Taff but found them "[a]t most . . . [revealing] instances in which treaters assumed [p]etitioner had received a different vaccine (Hepatitis B) that they believed could be associated with TM." Decision at 43. The Chief Special Master further concluded "no treaters ever proposed that [p]etitioner's injury . . . was likely caused by his prior Tdap vaccine." *Id.*

Petitioner argues the Chief Special Master's focus on the treaters' mistake in the type of vaccine, while ignoring the evidence that the treaters did consider vaccines as the cause of

petitioner's TM, "is not appropriate." Tr. at 62:7–9. As acknowledged by the Chief Special Master, Drs. Louie and Taff both mentioned I.J.'s injury possibly being associated with vaccines. Decision at 4, 6. Dr. Taff's note shows the treaters were not certain about what type of vaccine I.J. received, so Dr. Taff suggested "clarify[ing] I.J.'s immunization history," instead of "assuming" petitioner received a Hepatitis B vaccine. Med. Recs. 8-3 at 230 ("Will need to clarify patient's immunizations at occupational health, as there are case reports of TM following Hep B immunization."). Thus, the Chief Special Master's inference that "[a]t most, the record reveals . . . treaters assumed [p]etitioner had received a different vaccine (Hepatitis B) that they believed could be associated with TM" is not supported by the record. Decision at 43.

In reaching the conclusion "no treaters ever proposed that [p]etitioner's injury . . . was likely caused by his prior Tdap vaccine," the Chief Special Master disregarded I.J.'s treating physicians' opinions because the physicians either mistakenly recorded, or, in at least one instance, was not sure about, the type of vaccine I.J. received. In *Paluck*, petitioner's treating physician noted petitioner's neurodegeneration could have a "hereditary, toxic or metabolic etiolog[y]." *Paluck*, 786 F.3d at 1385. The special master "acknowledged the term 'toxic' is broad enough to include an injury caused by a vaccine" but disregarded the physician's opinion, because "[petitioner] ha[s] not addressed the other possible causes listed by [the physician]." *Id.* at 1385–86 (internal quotation marks omitted). The Federal Circuit found the special master "erred in disregarding contemporaneous statements from [petitioner's] treating physicians regarding the cause of his neurodegeneration," and "[i]t was arbitrary and capricious for the special master to wholly discount the probative value of [treaters'] statements simply because [the treaters] suggested that his condition could also potentially be due to alternative causes." *Id.* Here, the treaters' uncertainty about what type of vaccine I.J. received does not completely negate the probative value of the treaters' consideration of I.J.'s symptoms being related to his immunization history, especially given the "quite probative" value of treaters' opinions in *Althen* element two. *Capizzano*, 440 F.3d at 1326. Accordingly, it was arbitrary and capricious for the Chief Special Master to wholly discount the probative value of the treaters' statements simply because the treaters did not clarify I.J.'s immunization history. *Paluck*, 786 F.3d at 1386.

The Court makes no finding on whether the evidence of treaters' opinions ought to have changed the Chief Special Master's decision, nor is the Court trying to consider whether such evidence is sufficient to establish *Althen* element two. *Lampe*, 219 F.3d at 1360 (finding it is not the reviewing court's role "to reweigh the factual evidence"). As suggested by respondent, "if a medical provider provides a causation opinion about a particular vaccine causing an injury, that's particularly . . . deserving of great weight . . . . But here, . . . [what is before the Court is] less informed than a statement about a particular vaccine causing a particular reaction." Tr. at 60:20–61:1. The Court leaves the question to the Chief Special Master on remand.

C. Conclusion of *Althen* Element Two

The Court finds the Chief Special Master's factual findings supporting his *Althen* element two decision—"there was hardly any testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation" and "no treaters ever proposed that

[p]etitioner's injury . . . was likely caused by his prior Tdap vaccine"—were arbitrary and capricious. *Saunders*, 25 F.3d at 1033 (quoting *Munn*, 970 F.2d at 870 n.10) ("Fact findings are reviewed . . . under the arbitrary and capricious standard."); *Paluck*, 786 F.3d at 1380 ("Where, as here, a special master . . . misconstrues [petitioner's] medical records, and makes factual inferences wholly unsupported by the record, the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law."); *Andreu*, 569 F.3d at 1375 (concluding that the special master erred in disregarding probative testimony from a petitioner's treating physicians); *Mondello*, 132 Fed.Cl. at 323 (finding the special master "erred in her conclusion that petitioner's claim had to be dismissed for not providing any evidence of a theory of causation" when "there are [doctor's notes and records] and other pieces of evidence submitted by petitioner that arguably lend some support to his claim"). As the record contains at least some evidence suggesting "a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," the Chief Special Master's *Althen* element two is not supported by the record and the Court must remand the case.[29] *See id.*

VIII. The Chief Special Master's *Althen* Element Three Decision

The third element in *Althen* concerns temporal relationship between the vaccine and petitioner's injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Chief Special Master found "the record and evidence offered in this matter does support the conclusion that Petitioner's TM occurred in a medically acceptable timeframe, consistent with his causation theory." Decision at 43 (emphasis omitted). The Chief Special Master further noted "the onset timeframe was also consistent with Dr. Zamvil's persuasive testimony about the time it would take for a molecular mimicry-driven process to manifest

[29] The Chief Special Master also considered the existence of "pre-onset intercurrent respiratory infection" as a possible instigation cause of TM. Decision at 43. The Chief Special Master viewed the respiratory infection as "additional evidence that was not fully explained or distinguished by [p]etitioner, and thus it also undermined somewhat [p]etitioner's claim." *Id.* During oral argument, respondent explained to the Court "[r]espondent didn't set forth the respiratory infection as an alternate cause. That's something the Chief Special Master pointed out *sua sponte*." Tr. at 57:21–24. The Chief Special Master stated in full: "The evidence to support this alternative explanation is not itself particularly robust (certainly no infectious agent was identified in testing), and I do not propose that it establishes a stronger explanatory case than what [p]etitioner offered, or that (had the burden shifted to [r]espondent) it was preponderantly established as an alternative cause. But it is additional evidence that was not fully explained or distinguished by [p]etitioner, and thus it also undermined somewhat [p]etitioner's claim. But it *is* additional evidence that was not fully explained or distinguished by [p]etitioner, and thus it also undermined somewhat [p]etitioner's claim." Decision at 43 (emphasis original). It is unclear to the Court whether the Chief Special Master was shifting the burden to petitioner to rule out an alternative cause, or he was simply describing the record as being insufficient to review such an alternative cause. To the extent the Chief Special Master shifted the burden of ruling out an alternative cause onto petitioner in *Althen* element two, such shifting is permitted only "when evidence as to the *Althen* requirements is insufficient." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 n.3 (Fed. Cir. 2008) (citing *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1149–50 (Fed. Cir. 2007)); *see also Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1357–59 (Fed. Cir. 2006) (holding the petitioner's failure to eliminate other potential causes was fatal to the petition when she had not provided evidence of a proximate temporal relationship between the vaccine and her injury). Once the petitioner has established a prima facie case for entitlement to compensation and thus met the burden to prove causation-in-fact, the burden shifts to the government to prove "[b]y a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *de* Bazan, 539 F.3d at 1352 (citing 42 U.S.C. § 300aa–13(a)(1)(B); *Walther*, 485 F.3d at 1150). On remand, there may be reason for the Chief Special Master to further clarify his findings regarding the pre-onset respiratory infection.

neurologic harm." *Id.* Nevertheless, "because [p]etitioner's causation theory in this case was not sufficiently supported with preponderant evidence, the consistency of the onset timing in this case with [p]etitioner's theory does not aid [p]etitioner." *Id.*

Petitioner did not raise any issue on appeal regarding the Chief Special Master's *Althen* element three decision. *See* Mot. to Review. Respondent disagrees with the Chief Special Master's *Althen* element three decision, but does not contest this issue because petitioner "did not raise this issue on appeal." Tr. at 7:7–15 ("Respondent's position was that [p]etitioner did not meet *Althen* prong 3. However, the Chief Special Master found that [p]etitioner met prong 3 and did not raise that issue on appeal. So to the extent it wasn't raised on appeal, [r]espondent does not provide any sort of objection."). As the Chief Special Master's *Althen* element three decision is not a contested issue before the Court, the Court will not review it.

IX. Conclusion

As explained in greater detail *supra*, the Chief Special Master was arbitrary and capricious in deciding the Baxter study provided "far more comprehensive, contrary evidence" against petitioner's element one showing, finding "there was hardly *any* testing evidence (whether from serologic sampling or MRI imaging) that would establish the existence of inflammation," and finding "no treaters ever proposed that [p]etitioner's injury . . . was likely caused by his prior Tdap vaccine." Based on very recent Federal Circuit clarification, the Chief Special Master also erred in holding *Boatmon* abolished *Andreu*'s plausibility standard for *Althen* element one.

Accordingly, the following is ordered:

1. Petitioner's motion for review of the Special Master's 4 January 2021 decision is **GRANTED**;

2. This case is hereby **REMANDED** to the Chief Special Master for further proceedings consistent with this opinion.

IT IS SO ORDERED.

s/ Ryan T. Holte
RYAN T. HOLTE
Judge